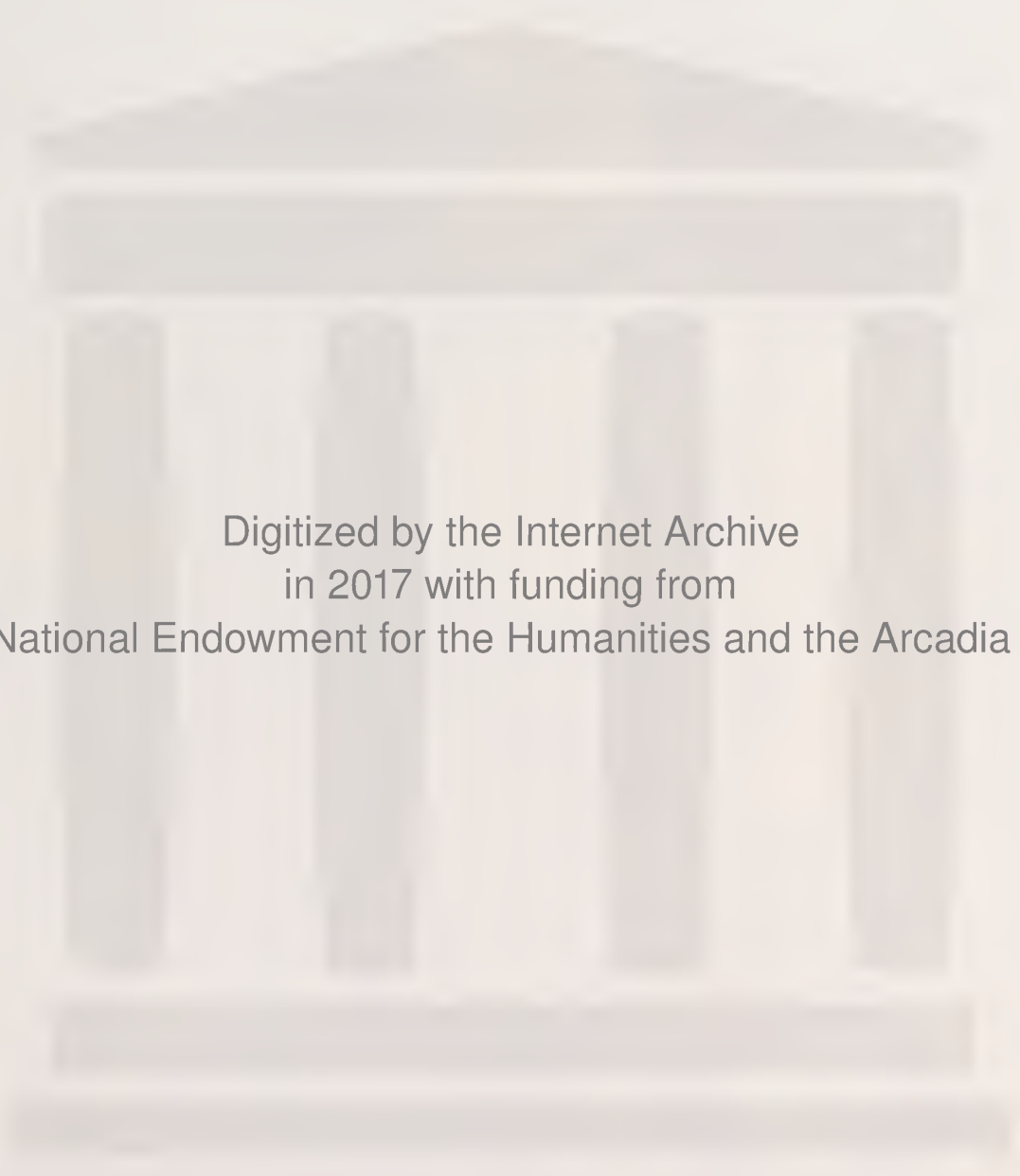


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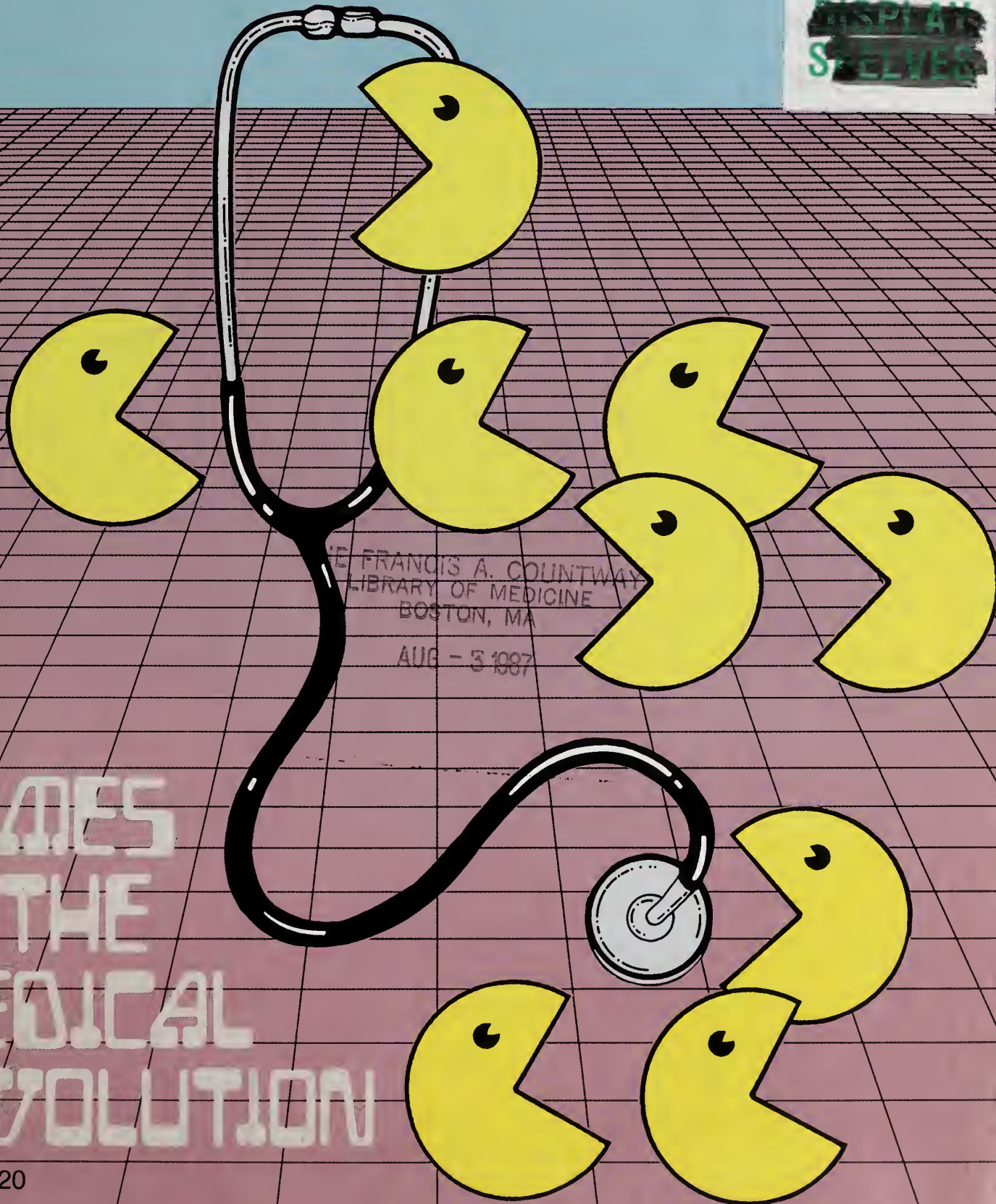
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July 1987

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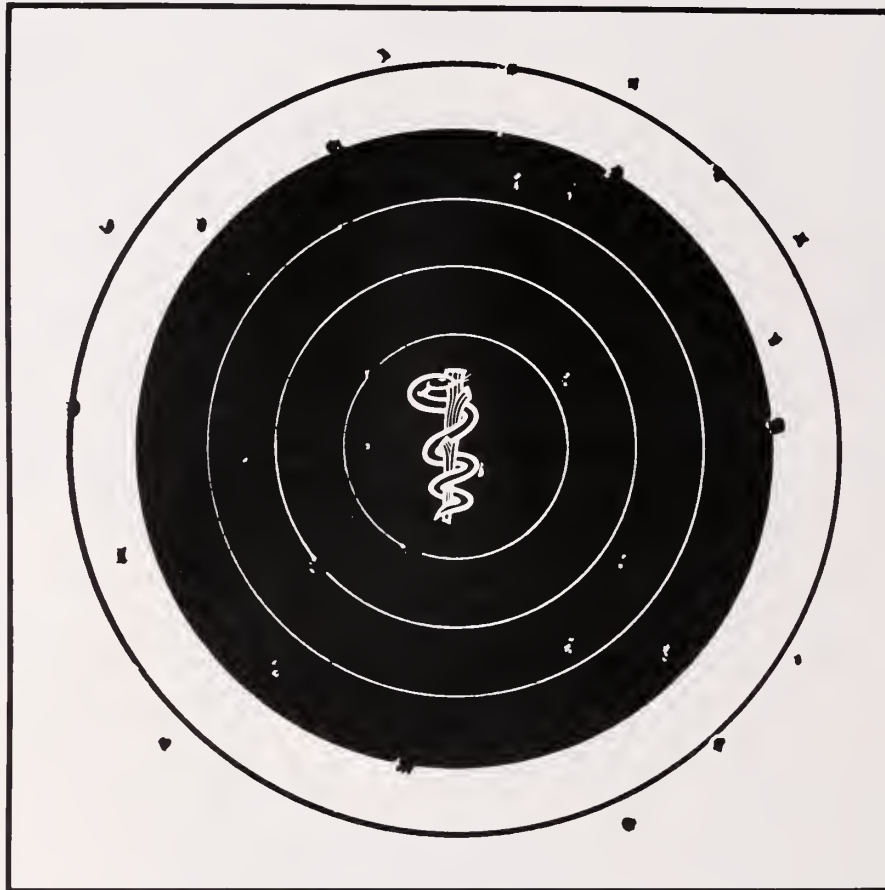
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CONTRAINDICATIONS

CARDIZEM is contraindicated in (1) patients with sick sinus syndrome except in the presence of a functioning ventricular pacemaker, (2) patients with second- or third-degree AV block except in the presence of a functioning ventricular pacemaker, and (3) patients with hypotension (less than 90 mm Hg systolic).

WARNINGS

1 Cardiac Conduction. CARDIZEM prolongs AV node refractory periods without significantly prolonging sinus node recovery time, except in patients with sick sinus syndrome. This effect may rarely result in abnormally slow heart rates (particularly in patients with sick sinus syndrome) or second- or third-degree AV block (six of 1,243 patients for 0.48%). Concomitant use of diltiazem with beta-blockers or digitalis may result in additive effects on cardiac conduction. A patient with Prinzmetal's angina developed periods of asystole (2 to 5 seconds) after a single dose of 60 mg of diltiazem.

2 Congestive Heart Failure. Although diltiazem has a negative inotropic effect in isolated animal tissue preparations, hemodynamic studies in humans with normal ventricular function have not shown a reduction in cardiac index nor consistent negative effects on contractility (dp/dt).

Experience with the use of CARDIZEM alone or in combination with beta-blockers in patients with impaired ventricular function is very limited. Caution should be exercised when using the drug in such patients.

3 Hypotension. Decreases in blood pressure associated with CARDIZEM therapy may occasionally result in symptomatic hypotension.

4 Acute Hepatic Injury. In rare instances, significant elevations in enzymes such as alkaline phosphatase, CPK, LDH, SGOT, SGPT, and other symptoms consistent with acute hepatic injury have been noted. These reactions have been reversible upon discontinuation of drug therapy. The relationship to CARDIZEM is uncertain in most cases, but probable in some. (See PRECAUTIONS.)

PRECAUTIONS

General. CARDIZEM (diltiazem hydrochloride) is extensively metabolized by the liver and excreted by the kidneys and in bile. As with any new drug given over prolonged periods, laboratory parameters should be monitored at regular intervals. The drug should be used with caution in patients with impaired renal or hepatic

function. In subacute and chronic dog and rat studies designed to produce toxicity, high doses of diltiazem were associated with hepatic damage. In special subacute hepatic studies, oral doses of 125 mg/kg and higher in rats were associated with histological changes in the liver which were reversible when the drug was discontinued. In dogs, doses of 20 mg/kg were also associated with hepatic changes; however, these changes were reversible with continued dosing.

Drug Interaction. Pharmacologic studies indicate that there may be additive effects in prolonging AV conduction when using beta-blockers or digitalis concomitantly with CARDIZEM. (See WARNINGS.)

Controlled and uncontrolled domestic studies suggest that concomitant use of CARDIZEM and beta-blockers or digitalis is usually well tolerated. Available data are not sufficient, however, to predict the effects of concomitant treatment, particularly in patients with left ventricular dysfunction or cardiac conduction abnormalities. In healthy volunteers, diltiazem has been shown to increase serum digoxin levels up to 20%.

Carcinogenesis, Mutagenesis, Impairment of

Fertility. A 24-month study in rats and a 21-month study in mice showed no evidence of carcinogenicity. There was also no mutagenic response in *in vitro* bacterial tests. No intrinsic effect on fertility was observed in rats.

Pregnancy. Category C. Reproduction studies have been conducted in mice, rats, and rabbits. Administration of doses ranging from five to ten times greater (on a mg/kg basis) than the daily recommended therapeutic dose has resulted in embryonic and fetal lethality. These doses, in some studies, have been reported to cause skeletal abnormalities. In the perinatal/postnatal studies, there was some reduction in early individual pup weights and survival rates. There was an increased incidence of stillbirths at doses of 20 times the human dose or greater.

There are no well-controlled studies in pregnant women; therefore, use CARDIZEM in pregnant women only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers. Diltiazem is excreted in human milk. One report suggests that concentrations in breast milk may approximate serum levels. If use of CARDIZEM is deemed essential, an alternative method of infant feeding should be instituted.

Pediatric Use. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Serious adverse reactions have been rare in studies carried out to date, but it should be recognized that patients with impaired ventricular function and cardiac conduction abnormalities have usually been excluded.

In domestic placebo-controlled trials, the incidence of adverse reactions reported during CARDIZEM therapy was not greater than that reported during placebo therapy.

The following represent occurrences observed in clinical studies which can be at least reasonably asso-

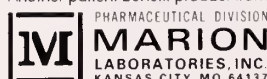
ciated with the pharmacology of calcium influx inhibition. In many cases, the relationship to CARDIZEM has not been established. The most common occurrences as well as their frequency at presentation are: edema (2.4%), headache (2.1%), nausea (1.9%), dizziness (1.5%), rash (1.3%), asthenia (1.2%). In addition, the following events were reported infrequently (less than 1%):

Cardiovascular:	Angina, arrhythmia, AV block (first degree), AV block (second or third degree — see conduction warning), bradycardia, congestive heart failure, flushing, hypotension, palpitations, syncope.
Nervous System:	Amnesia, gait abnormality, hallucinations, insomnia, nervousness, paresthesia, personality change, somnolence, tinnitus, tremor.
Gastrointestinal:	Anorexia, constipation, diarrhea, dysgeusia, dyspepsia, mild elevations of alkaline phosphatase, SGOT, SGPT, and LDH (see hepatic warnings), vomiting, weight increase.
Dermatologic:	Petechiae, pruritus, photosensitivity, urticaria.
Other:	Amblyopia, dyspnea, epistaxis, eye irritation, hyperglycemia, nasal congestion, nocturia, osteoarthral pain, polyuria, sexual difficulties.

The following postmarketing events have been reported infrequently in patients receiving CARDIZEM: alopecia, gingival hyperplasia, erythema multiforme, and leukopenia. However, a definitive cause and effect between these events and CARDIZEM therapy is yet to be established. Issued 7/86
See complete Professional Use Information before prescribing.

References: 1. Pepine CJ, Feldman RL, Hill JA, et al. Clinical outcome after treatment of rest angina with calcium blockers. Comparative experience during the initial year of therapy with diltiazem, nifedipine, and verapamil. *Am Heart J* 1983; 106(6): 1341-1347. 2. Shapiro W. Calcium channel blockers: Actions on the heart and uses in ischemic heart disease. *Consultant* 1984; 24(Dec): 150-159. 3. Johnston DL, Lesaway R, Humen DP, et al. Clinical and hemodynamic evaluation of propranolol in combination with verapamil, nifedipine and diltiazem in exertional angina pectoris: A placebo-controlled, double-blind, randomized, crossover study. *Am J Cardiol* 1985; 55: 680-687. 4. Cohn PF, Braunwald E. Chronic ischemic heart disease, in Braunwald E (ed): *Heart Disease. A Textbook of Cardiovascular Medicine*, ed 2. Philadelphia, WB Saunders Co, 1984, chap 39. 5. Schroeder JS. Calcium and beta blockers in ischemic heart disease. When to use which. *Mod Med* 1982; 50(Sept): 94-116.

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Helpful to many writers is *The Elements of Style* by William Strunk, Jr., and E. B. White, which emphasizes brevity, vigor and clarity.

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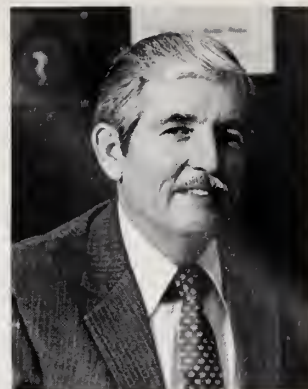
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EXECUTIVE DIRECTOR



*S. Lon Conner
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The 'Me First' Society

There are many indices of the weakening moral fiber of Americans, including but not limited to the more obvious ones in the news lately.

One of the most alarming examples of decay in the national character is one that directly affects the future of medical care: the erosion of the sense of individual responsibility.

We see this constantly in many ways. One that immediately comes to mind is the repeated poll finding that Americans would (A) love to have national health insurance with all their health care paid for by somebody but (B) not if *they* have to pay for it.

This is revealing of the destructive effects of the welfare mentality that seems to have reached virtually all segments of national life. Just as we find the organized poor loudly insisting that the country owes them a comfortable living, so do we see the rich demanding what is little different — national subsidy through tax exemption.

Senator Russell Long of Louisiana, who recently called it quits in Washington, probably had more experience than any living American with the attitudes of Americans here in the last decades of the 20th Century. He often described this, in that homey way of his, as being essentially this: "Don't tax him and don't tax me, tax that fellow behind the tree."

From the ghettos of Harlem to the boardrooms of major corporations, everyone seems to be intent on getting what they can from the "government," one way or another, and shifting their responsibility to the rest of the nation.

That was evident last year when Congress rewrote the income tax laws. It achieved this, against all odds, by simply sealing off Gucci Gulch (as the lobbyists' corridor is called) and achieving a kind of safety in numbers by hitting almost everyone.

Certainly the weakening of personal responsibility is blatantly evident in the national woes of Medicaid.

Family members feel no responsibility for their aged and ailing. On the contrary, they feel that it is another constitutional right of citizenship that the state warehouse their unwanted old folks.

At first blush, that may seem a separate problem from the recent misadventures of Gary Hart and Evangelist Jim Bakker. But some of the pundits in the field don't think so. Carlfred Broderick, a sociology professor at USC, says increased emphasis on what he calls "personhood," as opposed to duty, has helped unravel traditional family obligations.

Both Hart and Bakker can be seen, Professor Broderick says, as manifestations of the personhood cult. The focus in such cases, Broderick stresses, is on self, under the banner of "personal fulfillment." Tension in today's families, Broderick continues, derives largely from this same overemphasis on self to the exclusion of the family unit or society at large.

The "moral relativism" of our time, the abominable "me first" philosophy, derives directly from the antisocial theories of the German philosopher Friedrich Wilhelm Nietzsche (1844-1900), whose theories were also embraced by the Third Reich. Moral relativism can rationalize almost anything that anyone wants to rationalize. The monstrous doctrine that self-gratification is the primary goal of life has spread across this country, from the greedy malefactors on Wall Street to the militant "poverty pimps" in the inner cities. (That phrase, by the way, was coined by an iconoclastic black leader to describe those who feed on handouts to the organized poor, social workers and other intermediaries with a vested interest in the rising expectations of those who have made being poor a profession.)

Irene Goldenberg, a UCLA psychology professor, underscores the views of Professor Broderick. The cult of personality, she says, has brought about the selfish American view toward the responsibilities of marriage and other commitments. Placing self above all leaves nothing for any lasting union or any group interest. Today's children, she says, "are taking care of themselves first."

But before we blame it all on the young, let it be clearly noted that many of their elders have provided the role models for the ghastly notion that self is everything. Such a belief may have been sprouted in the fertile soil of the 60s but it now seems to cut across all lines of age and social standing.

As we move into the celebration of the bicentennial of our Constitution, to which millions pay lip service without reading or understanding, let it be said that this document emphasized individual responsibility.

Its negative proscriptions simply directed that no one, under whatever color of authority, may interfere with the peaceful work and individual duty of the nation's citizens as they pursue life, liberty and happiness.

It was a document of faith in the higher purpose served by man's duty to the common good. It was, as many have pointed out, a straightforward expression of the Calvinist belief in an ultimate moral right to which sinful man could aspire by working hard, living right and contributing to the good of his fellows and his country.

It was as far from moral relativism of the 1980s as is possible to imagine. It stressed freedom, yes, but the heavy *obligations* of freedom rather than the license of self-indulgence so fashionable in our land today.

How all this bears on the present state of the future of medicine seems to me fairly clear: failing a return to older moral codes and the uniquely American belief that each of us shares a heavy responsibility to pay our own way and shoulder the burdens of family, there is not going to be any surcease in the demand from all quarters that society owes us everything while we owe it nothing.

There have been times lately when the Founding Fathers would have wept and despaired of their handiwork in creating what John Gunther has called (in *Inside U.S.A.*) "the only country deliberately founded on a good idea."

Until the vogue idea of personhood and self, which has become a license for any behavior at all, is rededicated to the original concept of duty and responsibility as the first order of citizenship, many fear for the future of the Republic.

Maybe just thinking about Independence Day this month triggered this rather pessimistic sermon, but I know many physicians share these sentiments. ■

Lon

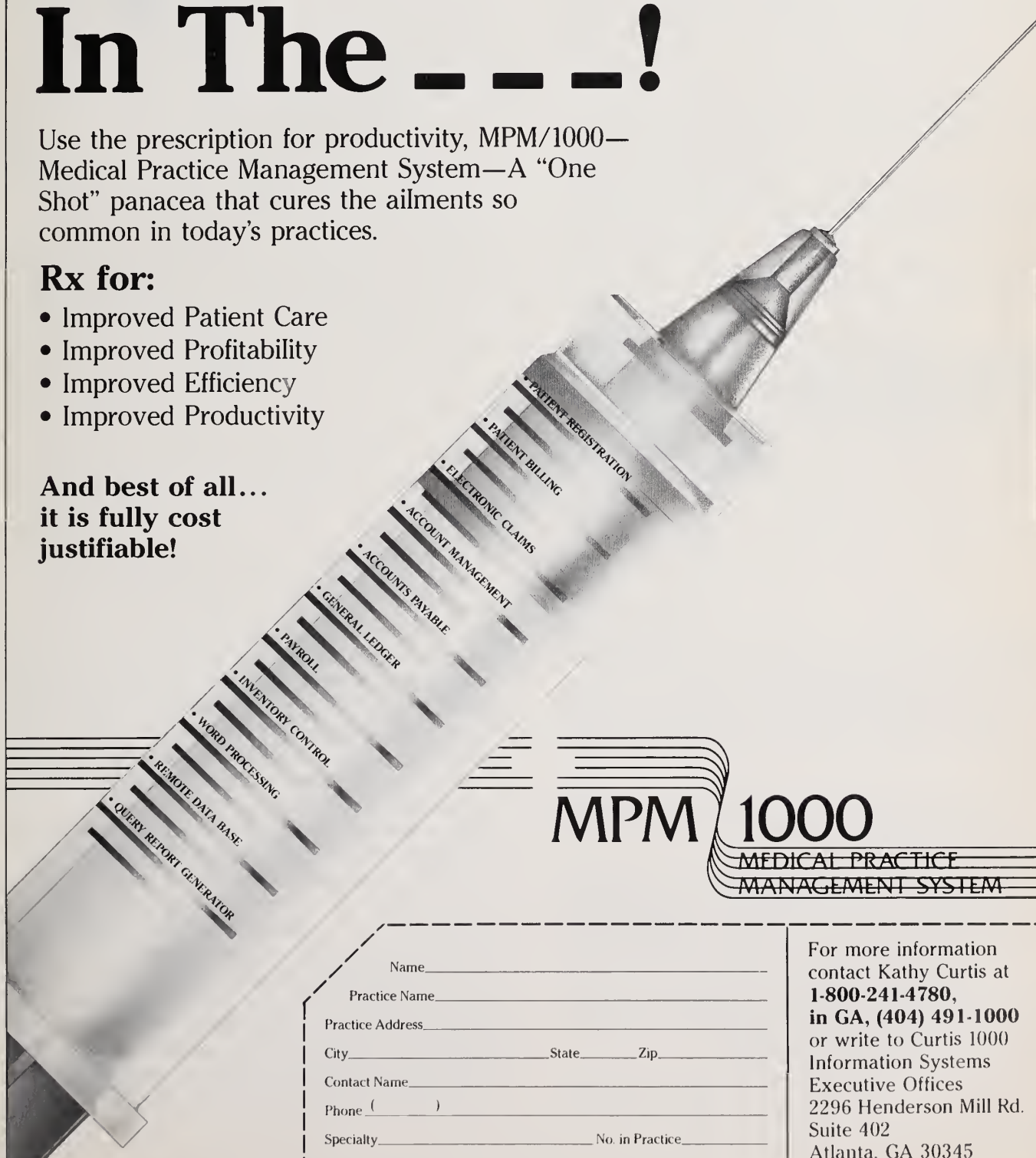
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*Carl A. Grote, Jr., M.D.
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Medicare Reform

There are two popular myths that tend to becloud any realistic discussion of the Medicare program and its perennial funding crisis:

The first myth is that beneficiaries are only receiving what they paid for in insurance while they were working;

The second myth is that health care is a new kind of right, an entitlement that goes along with being an American citizen.

The first myth has been systematically debunked by those whose job it is to keep books on the program: average benefits are many times the average pay-in.

The second myth owes its vitality to the country's 50-year experiment with the welfare state. After a generation or two of any welfare program, it is embraced as a fundamental privilege of citizenship, akin to life, liberty and the pursuit of happiness.

I said "welfare program" in reference to Medicare; in doing so, it is obvious that I am not a politician.

No Congressman would dare call it what it is, preferring to kowtow to the notion broadcast by the gray panthers that they have paid for this "insurance" (which it only remotely resembles) and that they have a right to perpetual care by the government because they earned it. And if they didn't earn all of it, they are still entitled to it as a right.

These fallacies are by now so deeply engrained in the public consciousness that to mention them is to risk being labeled anti-elderly.

Two AMA Councils — those on Legislation and Medical Service — spent years studying the problem of sound, fiscal reform of the Medicare system. Their study, completed and endorsed last year, was premised on the undeniable fact that Medicare is headed for bankruptcy; that each beneficiary is currently supported by four workers paying taxes, but that before the middle of the next century that one retiree will be supported by only two workers; that by the year 2010,

no more distant in one direction than the inception of Medicare in the other, Medicare will be \$1 trillion in debt. And so on.

The study (Report MM, AMA Board of Trustees, June 1986) was also prompted by the growing awareness of a glaring social inequity — the pay-as-you-go system is in fact an inter-generational transfer of resources, with the young being taxed to support the old, with the result that the young of America, for the first time in the nation's history, are said to be worse off than the preceding generation.

The system is also presently flawed, the AMA Council found, because it has no mechanism for equitable means testing; no provision for catastrophic experiences of the very kind that should be protected first in a true insurance program; and it is heavily burdened by government regulation (regulation, I hasten to add, that is primarily concerned with the rationing of care, although this is never admitted, of course).

The AMA Councils recommended in their report, embraced by the Board of Trustees and the House of Delegates, a proposed program that has these goals:

- Maintain access to affordable high quality health care for the elderly;
- Provide a prefunded program, instead of the present pay-as-you-go system;
- Provide for comprehensive protection, including catastrophic coverage;
- Provide for equitable means testing;
- Provide benefits via the private sector, through a variety of means, recognizing that a voucher would provide a beneficiary with a choice of his source of coverage;
- Allow for additional contributions to IRAs for funding supplemental elderly health care expense;
- Provide for a gradual increase in age of eligibility.

The AMA plan proposes, at some length, specific mechanisms for achieving these goals. But the Board of Trustees emphasized, as I do in outlining the plan, that alterations may be necessary. Still, it is a sincere, comprehensive attempt to bring order out of the present chaos.

It approaches this from the standpoint of true insurance, which the present Medicare program is not (although Congressmen insist it is), guaranteeing universal eligibility based on age but approaching the solution with an actuarially sound and prefunded concept.

Some details of the AMA plan:

- Provides catastrophic protection and means testing with out-of-pocket spending limits for most beneficiaries set at \$2,500 a year for individuals and \$3,750 for families (typically, husband and wife). The limits on out-of-pocket expenses are reached by combining a uniform coinsurance limit with a deductible that varies in amount relative to individual and family income.

Following enactment, each eligible individual and family (husband-wife) would receive an annual voucher for the purchase of an adequate benefit policy from an approved insurance carrier or other health plan. The voucher amount would differ according to geographic area and would reflect the applicable deductible and coinsurance.

The proposal allows for additional and significant contributions to IRAs, and for tax-free withdrawals from such IRAs for health expenses after reaching eligibility age.

There would be a gradual increase in age of eligibility for benefits under the new program, with that age increased from 65 to 67 at the rate of three months per year.

The new program would be financed by eliminating the current 1.45% payroll tax on employees and replacing it with an initial tax of 1.75% on adjusted gross income up to \$100,000.

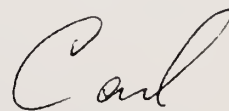
For about 95% of individuals, this would mean a net increase of three-tenths of one percentage point in their tax obligation.

The payroll tax on employers would be continued, with a modest (less than 1 percentage point) increase in the current 1.45% rate.

Although the initial tax rates for both employers and individuals under the Councils' proposal are slightly higher than existing rates under the Medicare program, the future rates for the new program are considerably less than those combined payroll and general revenue taxes (and Part B premium costs) which would be needed in the future to fund the current Medicare program on a fiscally sound basis.

The last words of the preceding paragraph are important: "to fund the current Medicare program on a fiscally sound basis."

I am not an actuary; I know little about the specifics of funding. But I do know that AMA's general approach, through an actuarially designed self-prefunded program, is essential if Medicare is to survive in a shape approaching that Congress intended when it launched the program. □



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Another Opinion

Editor, *Alabama Medicine*:

In his essay "Economics, Frigonomics and Medical Care," [*Alabama Medicine*, May 1987] Dr. Anderson mistakes his point about the ineffectiveness of market forces in controlling the cost of medical care. There has been no "cost" incentive since the onset of prepaid "medical insurance." Since the service is perceived as "free" at the time of service, there is no incentive to limit service to the bare essentials or to the cheapest provider. Instead, there is an incentive to get all you can for what you have already paid. This can only be corrected by restoring a system that applies cost at the time of service.

However, this would involve another conflict, and Dr. Anderson correctly recognizes the evils inherent in the idea that those who produce the wealth should derive greater benefit from it than those who don't. Thus the only way to be fair to everybody is to let the marvelously efficient and compassionate federal bureaucracy provide all health care, thus avoiding so much of the costs and inequities of the present system.

However, I foresee further problems arising. As economical medical care becomes universally available, it will soon be realized that a great deal of pain, suffering and expense is due to rugged individualists in such ways as drunken driving, speeding, passing on hills, not to mention the accidents in motorcycling, hang gliding, surfing, football and other violent sports.

Naturally, these must be outlawed, but the problem of transportation remains. This could best be solved by calling upon the expertise found in our federally funded mass transportation systems to set up a universal system of free transportation that would eliminate the necessity for the private automobile.

Also it would be recognized that much sickness is due to improper diet. The answer to this is also simple. Merely outlaw all private food outlets (groceries, restaurants, etc.) and set up a universal system of cafeterias so that each person is served a nutritious meal in a cafe operated by the federal bureaucracy. By means of the computer and the ever-present identification card, it would be practical to serve each person the diet he needs, rather than cater to his uninformed desires. Thus would the problems of malnutrition be eliminated.

Doubtless as we move toward perfection, other problems would surface which could also be solved by the beneficent federal bureaucracy. Thus we would soon attain to that state of bliss found in Russia, Red China and Cuba, and other totalitarian countries.

John R. Ledbetter, Jr., M.D.
Rogersville, AL 36652

Pneumocystis Carinii Pneumonia — Changing Status

LeRoy F. Harris, M.D.*

Abstract

The changing status of an infection is exemplified well by *Pneumocystis carinii* pneumonia. The protozoan infection originally was described in malnourished infant orphans, then in immunosuppressed hosts and recently in patients with the acquired immunodeficiency syndrome (AIDS). The classical clinical manifestations of abrupt onset of fever, dyspnea, tachypnea, cough, arterial hypoxemia and bilateral perihilar interstitial infiltrates on chest x-ray may be more insidious, not as pronounced or atypical in patients with AIDS. Diagnosis requires demonstration of characteristic organisms in Gomori methenamine silver or Giemsa stained lung tissue or pulmonary secretions obtained by open lung biopsy, needle aspiration or bronchoscopy. In AIDS patients bronchoscopy with bronchoalveolar lavage and


transbronchial biopsy has proven extremely efficacious. The first effective treatment of pneumocystis pneumonia was pentamidine which was supplanted by trimethoprim-sulfamethoxazole. Recent experience in patients with AIDS has revealed an astonishingly high incidence of adverse reactions associated with the administration of trimethoprim-sulfamethoxazole. Chemoprophylaxis with trimethoprim-sulfamethoxazole has been successful in patients with cancer and in bone marrow transplants but the frequent occurrence of toxic side effects renders this antibiotic unsuitable as a prophylactic agent in AIDS patients.

Pneumocystis Carinii Pneumonia — Changing Status

Nowhere is the changing status of an infection better exemplified than by *Pneumocystis carinii* pneumonia¹ and in a limited fashion our experience in

continued on page 17

* Clinical Associate Professor of Medicine, School of Primary Medical Care, University of Alabama in Huntsville, 410 Lowell, Huntsville, Alabama 35801.



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Blank space indicates that no such activity has been reported.

Table adapted from Facts and Comparisons (Nov.) 1984 and Catalano RB. The medical approach to management of pain caused by cancer. "Semin Oncol" 1975; 2; 379-92 and Reuler JB, et. al. The chronic pain syndrome: misconceptions and management. "Ann Intern Med" 1980; 93; 588-96.

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Revised, April 1982.

S685

1. *Hopkinson JH III: Curr Ther Res 24: 503-516, 1978*

2. *Beaver, WT Arch Intern Med, 141:293-300, 1981.*

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Pneumocystis Carinii Pneumonia

continued from page 14

Huntsville parallels this alteration. The infection also is assuming increasing importance because of its common occurrence in the acquired immunodeficiency syndrome (AIDS).² Thus, it behooves us as physicians to review pneumocystis infection because of the high likelihood of encountering it in our practices.

Materials and Methods

We reviewed the charts of all patients admitted to the three city and county hospitals of Huntsville, Alabama, for the seven year period, 1980-1986, with a diagnosis of *P. carinii* pneumonia. Pneumocystis pneumonia was diagnosed when three or more typical organisms were visualized in specimens of lung tissue or pulmonary secretions obtained by open lung biopsy or bronchoscopy.

Results

Table I describes the epidemiologic and clinical features of seven cases of *P. carinii* pneumonia. The first case was diagnosed in 1983, the next case in 1985 and the remaining five cases in 1986. The patients ranged in age from 26 to 66 years and averaged 42 years. All except one of the patients were male and all but two of the patients were afflicted with AIDS as an underlying disease. One patient each had breast cancer and lymphoma, respectively. Two of the patients were receiving chemotherapy for their malignancies and corticosteroids were being administered in only one patient. Dyspnea and cough were the most frequent symptoms followed by weight loss and fever. The patients' maximum temperature during the first 24 hours of hospitalization extended from 99.6 to 103° F and averaged 101.6° F.

Table II delineates the laboratory and radiologic data, diagnosis, treatment and outcome of seven cases of pneumocystis pneumonia. The leukocyte count on ad-

mission to the hospital ranged from 3300 to 8700 cells per cu mm and averaged 5914 cells per cu mm. The arterial blood oxygen level on room air extended from 37.6 to 86.9 mm Hg and averaged 63.2 mm Hg. Bilateral infiltrates were identified on chest x-ray in all but one patient and were located in diffuse, perihilar, upper lobe, mid lung and basilar patterns. Diagnosis was accomplished by open lung biopsy in two patients and by bronchoscopy in the other five patients. At bronchoscopy bronchoalveolar lavage detected organisms in three of five patients while transbronchial biopsy disclosed *P. carinii* in four of five patients. All patients except one initially were treated with trimethoprim-sulfamethoxazole but four patients were switched to pentamidine because of complications (rash, aplastic anemia, delirium, leukopenia) or lack of improvement. All patients receiving pentamidine tolerated the drug well. Two of seven patients died during hospitalization for a 28.5 percent mortality rate.

Discussion

Pneumocystis carinii is classified as a protozoan organism but never has been grown in vitro nor transmitted from humans to laboratory animals. In tissue *P. carinii* is identified by the Gomori methenamine silver stain as a thick walled cyst measuring four to six mm in diameter and containing up to eight oval bodies. The underlying lung tissue demonstrates foamy eosinophilic, honeycombed material located in the alveolar spaces. In lung imprints and bronchial washings trophozoite forms are visualized by the Giemsa stain. Infection in humans is limited to the lungs.³

Pneumocystis infection in humans first was described in 1938 and epidemics of *P. carinii* pneumonia called plasma cell interstitial pneumonitis occurred during and following World War II in malnourished infants housed in orphanages in Central Europe. During the 1960s and 1970s pneumocystis was described as a respiratory pathogen in immunosuppressed hosts including children with congenital immunodeficiency

TABLE I
Pneumocystis Carinii Pneumonia — Epidemiologic and Clinical Features

Case No.	Year of Diagnosis	Age (Years)	Sex	Underlying Disease	CMT*	CST†	Symptoms-Duration	Temperature (°F)‡
1	1983	66	M	AIDS	No	No	Dyspnea, weight loss-1 mo.	102.8
2	1985	36	M	AIDS	No	No	Dyspnea, cough, weight loss-5 mo	99.6
3	1986	26	M	AIDS	No	No	Dyspnea, cough, weight loss-2 wk	101.6
4	1986	31	M	AIDS	No	No	Dyspnea, cough, weight loss-5 wk	101.4
5	1986	39	M	AIDS	No	No	Cough, weight loss, fever-5 wk	102
6	1986	65	F	Breast Cancer	Yes	No	Cough, fever-2 d	101
7	1986	30	M	Lymphoma	Yes	Yes	Dyspnea, cough, fever-2 d	103

* Chemotherapy

† Corticosteroids

‡ Maximum temperature during first 24 h of hospitalization

states and leukemia, adults with malignancies and transplants and recipients of corticosteroids.⁴ Recently the incidence of pneumocystis infection has soared and AIDS has become the commonest disorder predisposing to it. *Pneumocystis carinii* pneumonia also is the commonest pulmonary and life threatening infection in AIDS patients.¹ In our series all cases except one were diagnosed in 1985 and 1986 and five of seven infections were associated with AIDS. Only two of our patients received chemotherapy and corticosteroids were administered to a single patient.

The classic clinical manifestations of *P. carinii* pneumonia are the abrupt onset of fever, dyspnea, tachypnea and nonproductive cough. Arterial hypoxemia invariably is encountered and chest x-ray discloses bilateral perihilar interstitial infiltrates described as a "butterfly" pattern. It has not been unusual to observe the onset of symptoms as corticosteroids are withdrawn or reduced in dosage.³ This classic picture is contrasted with that observed in patients with AIDS. The onset of symptoms is more insidious and in addition to fever, dyspnea and cough, malaise, chills and chest pain occur. Patients exhibit less hypoxemia and infiltrates on chest roentgenogram may be unilateral and confined to upper or lower lung fields. In up to five percent of cases the chest x-ray is clear.² Our experience in part corroborates this dichotomous picture. In patients without AIDS fever, dyspnea and cough appeared acutely while in AIDS patients symptoms were more chronic and also included weight loss. However, hypoxemia and chest x-ray findings were similar in both groups.

Definitive diagnosis of pneumocystis infection requires demonstration of characteristic organisms in lung tissue or pulmonary secretions. Prior to the AIDS epidemic open lung biopsy was the most productive method for diagnosis closely followed by closed (percutaneous) lung biopsy, lung (needle) aspiration and bronchoscopy with transbronchial biopsy.⁵ In AIDS patients bronchoscopy with bronchoalveolar lavage and transbronchial biopsy has proven extremely efficacious with diagnostic yields of greater than 93 percent. Both fixed tissue specimens and touch imprints should be stained, the latter with a rapid silver stain for same day results.² In our series open lung biopsy established the diagnosis in two patients while bronchoscopy was diagnostic in five patients. In these five patients bronchoalveolar lavage and transbronchial biopsy proved to be complementary procedures with one being often diagnostic when the other one was not and vice versa.

Noninvasive tests have been utilized to diagnose pneumocystis pneumonia with variable success. Arterial blood hypoxemia has been the hallmark of the infection but may be absent in up to 22 percent of AIDS patients and nine percent of patients without AIDS. The single breath diffusing capacity for carbon monoxide has been exquisitely sensitive but nonspecific and likewise, gallium lung scans exhibited a 98 percent sensitivity but only a 47 percent specificity. Of note, 10 percent of positive scans in patients in whom pneumocystis pneumonia subsequently was documented were accompanied by a simultaneous normal chest x-ray.⁶

Serologic tests for *P. carinii* pneumonia has not

TABLE II
Pneumocystis Carinii Pneumonia — Laboratory and Radiologic Data, Diagnosis, Treatment and Outcome

Case No.	WBC (Cells/cu mm)*	PO ₂ (mmHg)†	Chest X-Ray	Diagnostic Procedure	Treatment-Complications	Outcome
1	8000	47.5	Bilateral perihilar interstitial infiltrates	OLB‡	SXT§-rash, aplastic anemia pentamidine	Live
2	3700	86.9	Diffuse bilateral infiltrates	BAL TBBx #	SXT	Live
3	3300	66.2	Bilateral upper lobe patchy infiltrates	BAL TBBx	SXT-delirium, leukopenia pentamidine	Live
4	4800	58.5	Right upper lobe infiltrate	BAL TBBx	pentamidine	Die
5	7700	82.6	Left mid lung and right lower lobe infiltrates	BAL TBBx	SXT-leukopenia pentamidine	Live
6	5200	37.6	Bilateral patchy infiltrates	OLB	SXT	Die
7	8700	63.3	Bilateral basilar interstitial infiltrates	BAL TBBx	SXT-no improvement pentamidine	Live

* Leukocyte count on admission to hospital

† Arterial blood oxygen level on room air

‡ Open lung biopsy

§ Trimethoprim-sulfamethoxazole

|| Bronchoalveolar lavage performed during bronchoscopy

Transbronchial biopsy performed during bronchoscopy

proven diagnostically useful. Antibody to *P. carinii* has been detected in up to 80 percent of normal children by age four years and seroconversion or increase in antibody titer frequently does not occur during active infection. Determination of pneumocystis antigen has yielded discordant results. An early study detected antigen in 79 to 95 percent of patients with pneumocystis pneumonia but in no normal control subjects nor in patients with pneumonitis due to other pathogens.⁷ Unfortunately, more recent studies have not confirmed these favorable results.¹

A vigorous diagnostic approach has been recommended for pulmonary infiltrates in immunocompromised hosts in general and in AIDS patients in particular. Although empiric antipneumocystis therapy has been advocated in high risk patients with a compatible clinical picture other etiologies of the pulmonary pathology exist and will be missed with empiric treatment. An invasive procedure is urged and both in our experience and the experience of others bronchoscopy with bronchoalveolar lavage and transbronchial biopsy has proven efficacious and safe.³ Preliminary results of sputum examination and nonbronchoscopic bronchoalveolar lavage for the detection of *P. carinii* in patients with AIDS are encouraging and deserve further study.^{8,9}

The first effective treatment of pneumocystis pneumonia was pentamidine, an aromatic diamidine supplied in the United States as the isethionate salt.¹⁰ Pentamidine reduced the mortality rate from 50 percent to under four percent during epidemics in Central European infants⁴ and from 100 percent to under 40 percent in immunocompromised patients. Pentamidine is administered as a single daily dose of four mg per kg body weight by the intramuscular or intravenous route. Adverse reactions include pain at the injection site, hypotension, nephrotoxicity, bone marrow depression, hepatotoxicity, hypoglycemia and hyperglycemia.¹⁰

Approximately 20 years ago treatment with the folate antagonists, pyrimethamine combined with either sulfadoxine or sulfidiazine, was demonstrated to be efficacious. In the last decade another pair of folate antagonists, the combination of trimethoprim-sulfamethoxazole, has emerged as the treatment of the choice for *P. carinii* pneumonia. The antibiotic is administered orally or intravenously in a dose of 20 mg per kg body weight of trimethoprim and 100 mg per kg body weight of sulfamethoxazole divided into three or four equal portions and continued for 10-14 days.³ In a comparative study in children with cancer trimethoprim-sulfamethoxazole proved as effective as and produced fewer toxic side effects than pentamidine. The overall mortality rate of 24 percent was similar in both groups.¹¹

More recent experience with the use of trimethoprim-sulfamethoxazole for pneumocystis pneumonia in patients with AIDS has revealed an astonishingly

high incidence of adverse reactions consisting of fever, severe rash, nephrotoxicity, bone marrow depression, hepatotoxicity and delirium. A prospective trial showed a higher (but not significantly so) fatality rate in AIDS patients treated with trimethoprim-sulfamethoxazole rather than pentamidine and an overall mortality rate of 15 percent. The incidence of toxic side effects was equal in both treatment groups.¹² The optimal duration of therapy is unresolved but extension of the conventional 10 to 14 day regimen to three to four weeks is recommended. Even after such prolonged therapy two-thirds of patients will have persistent *P. carinii* on repeat bronchoscopy.¹ For patients not responding to one antibiotic at the end of four days of treatment change to the other antimicrobial agent is advocated. Reduction of immunosuppressive therapy may enhance the chance of survival.³ In our experience trimethoprim-sulfamethoxazole treatment was associated with a high incidence of adverse reactions or lack of response while therapy with pentamidine was tolerated well and effective.

Because of recurrence rates of pneumocystis pneumonia of up to five percent in patients with malignancies and 50 percent in AIDS patients, chemoprophylaxis has been suggested. Trimethoprim-sulfamethoxazole has been utilized successfully as a prophylactic agent in patients with cancer¹³ and in bone marrow transplants¹ administered in a daily dose of 5 mg per kg body weight of trimethoprim and 25 mg per kg body weight of sulfamethoxazole. Unfortunately the frequent occurrence of toxic side effects renders this antibiotic unsuitable as a prophylactic agent for patients with AIDS.¹ □

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Games of the “Medical Revolution”

David A. McLain, M.D.

There are many new games that have been introduced to medicine in the past several years. These games have made the practice of medicine more challenging than ever.

Not only do we have to try to diagnose and treat our patients accurately and with compassion and discuss their problems with them and their family members, but we also now have many games that we must play. For those who haven't been keeping track, here are some of the newer games that have been introduced.

Heads You Lose, Tails You Lose: This is a game for three players that's fun for two. Roll the dice and the loser is the physician. The other two players are an attorney and an insurance executive. The game consists of a number of diagnostic and therapeutic decisions for the physician. "A woman presents with headache and blurred vision — do you want a CAT scan of the brain?" If you say "yes," the insurance executive sends you a letter asking why you wanted this unnecessary test? Was it preapproved? Did the patient meet the criteria?

If you say "no" to the CAT scan, you receive a letter from the attorney asking how you could be so incompetent as to miss a brain tumor in this woman. Did you know you were liable for not ordering a test that was clearly indicated? The game proceeds with the physician cutting back his practice to limit liability, paying high malpractice premiums, and spending hours writing insurance companies and taking depositions.

Play Doctor Game: Don't get the wrong idea. This isn't an x-rated game. To play this game invite your pharmacist, a nurse that works for an insurance company's preadmission department, an insurance auditor, *anyone!* Anyone can play Doctor these days. What took you years of hard work to obtain can be theirs in no time. All they need is a book!

The game starts in your office with a sick patient. You've taken care of this woman for 20 years and you know her like one of your family. She's sick and you know it. Before you put her in the hospital, however, you must first call Pittsburgh! Call Pittsburgh? Yes,

continued on page 25

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A recent double-blind, placebo-controlled, crossover study in 138 hypertensive patients² revealed that INDERAL LA has a side effects profile unsurpassed by atenolol or metoprolol — which shows how well-tolerated once-daily INDERAL LA can be.

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Fifty-nine percent of the time, INDERAL LA stood on its own.

The patients in the nationwide compliance trial were no different from yours. Generally when the antihypertensive regimen is complicated, compliance may become a problem. So, the effectiveness of INDERAL LA as once-daily monotherapy is a big plus. Of the remaining hypertensives in the program, 36% were treated merely with the addition of a diuretic to INDERAL LA.

For the noncompliant patients in your practice, INDERAL LA may well be the answer.

Almost 20,000 of the patients in the nationwide compliance trial were identified as having been noncompliant with their previous antihypertensive therapy. Their physicians reported that 88% showed improved compliance when placed on once-daily INDERAL LA.

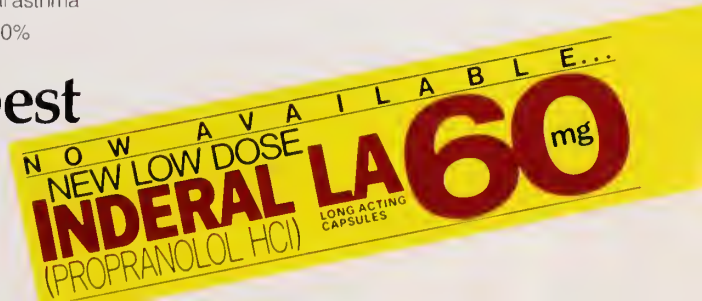
Control, comfort, and compliance

ONCE-DAILY
INDERAL[®] LA
(PROPRANOLOL HCl) LONG ACTING CAPSULES

Like conventional INDERAL Tablets, INDERAL LA should not be used in the presence of congestive heart failure, sinus bradycardia, cardiogenic shock, heart block greater than first degree, and bronchial asthma.

*After a 30-day trial with INDERAL LA, physicians reported that 90% of the patients would remain on INDERAL LA.

**The one you know best
keeps looking better**



Please see next page for brief summary of prescribing information.

The one you know best keeps looking better

BRIEF SUMMARY (FOR FULL PRESCRIBING INFORMATION, SEE PACKAGE CIRCULAR)

INDERAL® LA brand of propranolol hydrochloride (Long Acting Capsules)

DESCRIPTION. Inderal LA is formulated to provide a sustained release of propranolol hydrochloride. Inderal LA is available as 60 mg, 80 mg, 120 mg, and 160 mg capsules.

CLINICAL PHARMACOLOGY. Inderal is a nonselective, beta-adrenergic receptor-blocking agent possessing no other autonomic nervous system activity. It specifically competes with beta-adrenergic receptor-stimulating agents for available receptor sites. When access to beta-receptor sites is blocked by Inderal, the chronotropic, inotropic, and vasodilator responses to beta-adrenergic stimulation are decreased proportionately.

Inderal LA Capsules (60, 80, 120, and 160 mg) release propranolol HCl at a controlled and predictable rate. Peak blood levels following dosing with Inderal LA occur at about 6 hours and the apparent plasma half-life is about 10 hours. When measured at steady state over a 24-hour period the areas under the propranolol plasma concentration-time curve (AUCs) for the capsules are approximately 60% to 65% of the AUCs for a comparable divided daily dose of Inderal Tablets. The lower AUCs for the capsules are due to greater hepatic metabolism of propranolol, resulting from the slower rate of absorption of propranolol. Over a twenty-four (24) hour period, blood levels are fairly constant for about twelve (12) hours then decline exponentially.

Inderal LA should not be considered a simple mg-for-mg substitute for conventional propranolol and the blood levels achieved do not match (are lower than) those of two to four times daily dosing with the same dose. When changing to Inderal LA from conventional propranolol, a possible need for retitration upwards should be considered especially to maintain effectiveness at the end of the dosing interval. In most clinical settings, however, such as hypertension or angina where there is little correlation between plasma levels and clinical effect, Inderal LA has been therapeutically equivalent to the same mg dose of conventional Inderal as assessed by 24-hour effects on blood pressure and on 24-hour exercise responses of heart rate, systolic pressure and rate pressure product. Inderal LA can provide effective beta blockade for a 24-hour period.

INDICATIONS AND USAGE. Hypertension: Inderal LA is indicated in the management of hypertension. It may be used alone or used in combination with other antihypertensive agents, particularly a thiazide diuretic. Inderal LA is not indicated in the management of hypertensive emergencies.

Angina Pectoris Due to Coronary Atherosclerosis: Inderal LA is indicated for the long-term management of patients with angina pectoris.

Migraine: Inderal LA is indicated for the prophylaxis of common migraine headache. The efficacy of propranolol in the treatment of a migraine attack that has started has not been established and propranolol is not indicated for such use.

Hypertrophic Subaortic Stenosis: Inderal LA is useful in the management of hypertrophic subaortic stenosis, especially for treatment of exertional or other stress-induced angina, palpitations, and syncope. Inderal LA also improves exercise performance. The effectiveness of propranolol hydrochloride in this disease appears to be due to a reduction of the elevated outflow pressure gradient which is exacerbated by beta-receptor stimulation. Clinical improvement may be temporary.

CONTRAINDICATIONS. Inderal is contraindicated in 1) cardiogenic shock, 2) sinus bradycardia and greater than first-degree block, 3) bronchial asthma, 4) congestive heart failure (see WARNINGS) unless the failure is secondary to a tachyarrhythmia treatable with Inderal.

WARNINGS. CARDIAC FAILURE. Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive heart failure, and its inhibition by beta blockade may precipitate more severe failure. Although beta blockers should be avoided in overt congestive heart failure, if necessary, they can be used with close follow-up in patients with a history of failure who are well compensated and are receiving digitalis and diuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitalis on heart muscle.

IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta blockers can, in some cases, lead to cardiac failure. Therefore, at the first sign or symptom of heart failure, the patient should be digitalized and/or treated with diuretics, and the response observed closely, or Inderal should be discontinued (gradually, if possible).

IN PATIENTS WITH ANGINA PECTORIS, there have been reports of exacerbation of angina and, in some cases, myocardial infarction, following abrupt discontinuance of Inderal therapy. Therefore, when discontinuance of Inderal is planned, the dosage should be gradually reduced over at least a few weeks, and the patient should be cautioned against interruption or cessation of therapy without the physician's advice. If Inderal therapy is interrupted and exacerbation of angina occurs, it is usually advisable to reinstitute Inderal therapy and take other measures appropriate for the management of unstable angina pectoris. Since coronary artery disease may be unrecognized, it may be prudent to follow the above advice in patients considered at risk of having occult atherosclerotic heart disease who are given propranolol for other indications.

Nonallergic Bronchospasm (eg, chronic bronchitis, emphysema) — PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD IN GENERAL NOT RECEIVE BETA BLOCKERS. Inderal should be administered with caution since it may block bronchodilation produced by endogenous and exogenous catecholamine stimulation of beta receptors.

MAJOR SURGERY. The necessity or desirability of withdrawal of beta-blocking therapy prior to major surgery is controversial. It should be noted, however, that the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.

Inderal (propranolol HCl), like other beta blockers, is a competitive inhibitor of beta-receptor agonists and its effects can be reversed by administration of such agents, eg, dobutamine or isoproterenol. However, such patients may be subject to protracted severe hypotension. Difficulty in starting and maintaining the heartbeat has also been reported with beta blockers.

DIABETES AND HYPOLYCEMIA. Beta blockers should be used with caution in diabetic patients if a beta-blocking agent is required. Beta blockers may mask tachycardia occurring with hypoglycemia, but other manifestations such as dizziness and sweating may not be significantly affected. Following insulin-induced hypoglycemia, propranolol may cause a delay in the recovery of blood glucose to normal levels.

THYROTOXICOSIS. Beta blockade may mask certain clinical signs of hyperthyroidism. Therefore, abrupt withdrawal of propranolol may be followed by an exacerbation of symptoms of hyperthyroidism, including thyroid storm. Propranolol may change thyroid function tests, increasing T₄ and reverse T₃ and decreasing T₃.

IN PATIENTS WITH WOLFF-PARKINSON-WHITE SYNDROME, several cases have been reported in which, after propranolol, the tachycardia was replaced by a severe bradycardia requiring a demand pacemaker. In one case, this resulted after an initial dose of 5 mg propranolol.

PRECAUTIONS. GENERAL. Propranolol should be used with caution in patients with impaired hepatic or renal function. Inderal (propranolol HCl) is not indicated for the treatment of hypertensive emergencies.

Beta-adrenoreceptor blockade can cause reduction of intraocular pressure. Patients should

be told that Inderal may interfere with the glaucoma screening test. Withdrawal may lead to a return of increased intraocular pressure.

CLINICAL LABORATORY TESTS. Elevated blood urea levels in patients with severe heart disease, elevated serum transaminase, alkaline phosphatase, lactate dehydrogenase.

DRUG INTERACTIONS. Patients receiving catecholamine-depleting drugs such as reserpine should be closely observed if Inderal is administered. The added catecholamine-blocking action may produce an excessive reduction of resting sympathetic nervous activity which may result in hypotension, marked bradycardia, vertigo, syncopal attacks, or orthostatic hypotension.

Caution should be exercised when patients receiving a beta blocker are administered a calcium-channel-blocking drug, especially intravenous verapamil, for both agents may depress myocardial contractility or atrioventricular conduction. On rare occasions, the concomitant intravenous use of a beta blocker and verapamil has resulted in serious adverse reactions, especially in patients with severe cardiomyopathy, congestive heart failure or recent myocardial infarction.

Aluminum hydroxide gel greatly reduces intestinal absorption of propranolol. Ethanol slows the rate of absorption of propranolol.

Phenytoin, phenobarbital, and rifampin accelerate propranolol clearance.

Chlorpromazine, when used concomitantly with propranolol, results in increased plasma levels of both drugs.

Antipyrene and lidocaine have reduced clearance when used concomitantly with propranolol.

Thyroxine may result in a lower than expected T₃ concentration when used concomitantly with propranolol.

Cimetidine decreases the hepatic metabolism of propranolol, delaying elimination and increasing blood levels.

Theophylline clearance is reduced when used concomitantly with propranolol.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY. Long-term studies in animals have been conducted to evaluate toxic effects and carcinogenic potential. In 18-month studies in both rats and mice, employing doses up to 150 mg/kg/day, there was no evidence of significant drug-induced toxicity. There were no drug-related tumorigenic effects at any of the dosage levels. Reproductive studies in animals did not show any impairment of fertility that was attributable to the drug.

PREGNANCY. Pregnancy Category C. Inderal has been shown to be embryotoxic in animal studies at doses about 10 times greater than the maximum recommended human dose. There are no adequate and well-controlled studies in pregnant women. Inderal should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

NURSING MOTHERS. Inderal is excreted in human milk. Caution should be exercised when Inderal (propranolol HCl) is administered to a nursing woman.

PEDIATRIC USE. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS. Most adverse effects have been mild and transient and have rarely required the withdrawal of therapy.

Cardiovascular. Bradycardia, congestive heart failure, intensification of AV block, hypotension, paresthesia of hands, thrombocytopenic purpura, arterial insufficiency, usually of the Raynaud type.

Central Nervous System. Light-headedness, mental depression manifested by insomnia, lassitude, weakness, fatigue, reversible mental depression progressing to cataplexy, visual disturbances, hallucinations, vivid dreams, an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics. For immediate formulations, fatigue, lethargy and vivid dreams appear dose related.

Gastrointestinal. Nausea, vomiting, epigastric distress, abdominal cramping, diarrhea, constipation, mesenteric arterial thrombosis, ischemic colitis.

Allergic. Pharyngitis and agranulocytosis, erythematous rash, fever combined with aching and sore throat, laryngospasm and respiratory distress.

Respiratory. Bronchospasm.

Hematologic. Agranulocytosis, nonthrombocytopenic purpura, thrombocytopenic purpura.

Auto-Immune. In extremely rare instances, systemic lupus erythematosus has been reported.

Miscellaneous. Alopecia, LE-like reactions, photosensitivity rashes, dry eyes, male impotence, and Peyronie's disease have been reported rarely. Oculocutaneous reactions involving the skin, serous membranes and conjunctivae reported for a beta blocker (practolol) have not been associated with propranolol.

DOSE AND ADMINISTRATION. Inderal LA provides propranolol hydrochloride in a sustained-release capsule for administration once daily. If patients are switched from Inderal Tablets to Inderal LA Capsules, care should be taken to assure that the desired therapeutic effect is maintained. Inderal LA should not be considered a simple mg-for-mg substitute for Inderal. Inderal LA has different kinetics and produces lower blood levels. Retitration may be necessary, especially to maintain effectiveness at the end of the 24-hour dosing interval.

HYPERTENSION. Dosage must be individualized. The usual initial dosage is 80 mg Inderal LA once daily, whether used alone or added to a diuretic. The dosage may be increased to 120 mg once daily or higher until adequate blood-pressure control is achieved. The usual maintenance dosage is 120 to 160 mg once daily. In some instances a dosage of 640 mg may be required. The time needed for full hypertensive response to a given dosage is variable and may range from a few days to several weeks.

ANGINA PECTORIS. Dosage must be individualized. Starting with 80 mg Inderal LA once daily, dosage should be gradually increased at three- to seven-day intervals until optimal response is obtained. Although individual patients may respond at any dosage level, the average optimal dosage appears to be 160 mg once daily in angina pectoris. The value and safety of dosage exceeding 320 mg per day have not been established.

If treatment is to be discontinued, reduce dosage gradually over a period of a few weeks (see WARNINGS).

MIGRAINE. Dosage must be individualized. The initial oral dose is 80 mg Inderal LA once daily. The usual effective dose range is 160-240 mg once daily. The dosage may be increased gradually to achieve optimal migraine prophylaxis. If a satisfactory response is not obtained within four to six weeks after reaching the maximal dose, Inderal LA therapy should be discontinued. It may be advisable to withdraw the drug gradually over a period of several weeks.

HYPERTROPHIC SUBAORTIC STENOSIS. 80-160 mg Inderal LA once daily.

PEDIATRIC DOSAGE. At this time the data on the use of the drug in this age group are too limited to permit adequate directions for use.

*The appearance of these capsules is a registered trademark of Ayerst Laboratories.

REFERENCES:

1. Inderal LA National Compliance Evaluation Program. Data on file, Ayerst Laboratories.
2. Ravid M, Lang R, Jutrin I: The relative antihypertensive potency of propranolol, oxprenolol, atenolol, and metoprolol given once daily. *Arch Intern Med* 1985; 145:1321-1323.

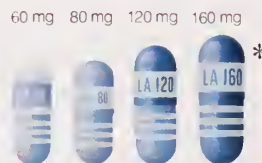
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New York, NY 10017

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ONCE-DAILY
INDERAL® LA
(PROPRANOLOL HCl)
LONG ACTING CAPSULES



REPORT OF THE BOARD OF TRUSTEES

Report: YY
(A-87)

Subject: Prevention and Control of AIDS -
An Interim Report

Presented by: Alan R. Nelson, M.D., Chairman

Referred to: Reference Committee E
(Alfred J. Clementi, M.D., Chairman)

Introduction

Responding sensitively, intelligently, and effectively to the growing AIDS crisis is one of the crucial public health problems facing the nation. Prevention and control of the disease must be an essential part of that response because there is, at present, no known cure for AIDS patients.

Recommendations in this report have as their foundation an overriding concern for a judicious balance between the well-being of HIV positive patients and the protection of the public health. These recommendations are based upon the best information and data available at present. The AMA will continuously monitor and analyze developments in AIDS and update AMA policy and recommendations as dictated by advances in knowledge.

Education continues to be the major weapon against spread of HIV infection. Physicians should assume the leadership role in educating themselves, their patients and the public. Individuals in society also must assume responsibility for being well-informed and for actions that affect their own health and the health of others. In developing this report, the Board emphasizes the need for concerted and cooperative efforts by all members of society in the fight against AIDS. The recommendations outlined below are designed to help in successfully confronting this challenge to society's well-being.

I. Background

A. The Current Climate

It is estimated that five to ten million people are infected with HIV virus worldwide. AIDS has been reported in more than one hundred countries. In the United States HIV-infected individuals may number one and one-half (1.5) million, approximately 35,000 of whom have been reported to suffer from AIDS and more than 20,000 of whom are dead.

The U.S. Public Health Service has projected that by 1991 there may be 323,000 reported patients with AIDS and as many as 200,000 of them may be dead by that time. In addition, conversion rates of seropositive people to AIDS status now appear to be higher than early preliminary estimates. Originally under 20% were thought to convert. It now appears that, without treatment advances, a much higher percentage will develop the disease.

Seventeen percent of the AIDS cases have been intravenous drug abusers; 66% have been homosexual/bisexual men; 8% have been homosexual male IV drug users; female, heterosexual male, and pediatric victims infected by the transfusion of blood or blood products, sexual contact, or prenatally in the case of infants, account for the bulk of the balance.

Polls indicate that AIDS has become the highest priority health concern of the American public, ahead of heart disease and cancer. It has already caused changes in a variety of public attitudes. Sexual abstinence, monogamous relationships, and the use of condoms are being widely promoted in the media by public officials and many private organizations. IV drug abusers are being counseled to use clean needles and to avoid sharing needles. Education on the sexual transmission of the AIDS virus is being extended to school children. The nation is more sensitive to the rights of those afflicted with the disease to be free from discrimination, regardless of the manner by which they became infected.

B. Historical Control Measures for Infectious Diseases

A primary mode of transmission of AIDS is through sexual contact, and the control efforts for sexually transmitted diseases (STD) that have been instituted in the past are sources of analogies for prevention and control of AIDS. National programs to control STDs were established during the beginning of World War I. For the following 50 years the focus was almost exclusively on the control of syphilis and its complications. During World War II rapid treatment centers for syphilis and gonorrhea were established. Public health officials instituted limited contact-tracing, had the authority to close sex bars and clubs, to order tests for prostitutes, and, most importantly, had effective therapy to offer. Widespread availability of penicillin led to the dissolution of the rapid treatment centers and of the clinical speciality, syphilology. Every state in the Union at one time required all persons seeking marriage licenses to be tested for syphilis. During the 1950s and 1960s federal assistance programs continued to support contact-tracing, serological screening, and patient education.

In the late 1960s public health officials were concerned about the rapidly escalating cases of gonorrhea, and projects were instituted to increase case-finding and contact-tracing. In 1972

financial assistance for STD control by the federal government was dramatically increased and by 1982 gonorrhea accounted for nearly three-fourths of the federal STD dollar. During the 1970s gonorrhea control efforts evolved through overlapping phases that included objectives to lower disease incidence and the occurrence of drug-resistant bacteria, focused screening on high-risk patients, intensified follow-up of treatment failures, and used patient counseling as a means of increasing compliance with therapy and improving contact-tracing. The latter was deemed especially important since the large numbers of gonorrhea cases precluded the intensive follow-up of each infected case that had been characteristic of the syphilis era.

In 1982 the World Health Organization/Pan American Health Organization (WHO/PAHO) identified the following key objectives for intervention to reduce STDs:

1. To minimize disease exposure by reducing sexual intercourse with persons who have a high probability of infection.
2. To prevent infection by increasing the use of condoms or other prophylactic barriers.
3. To detect and cure disease by implementing screening programs, providing effective diagnostic and treatment facilities, and promoting health-seeking behaviors.
4. To limit complications of infections by providing early treatment to symptomatic and asymptomatic infected individuals.
5. To limit disease transmission within the community through the above efforts.

These objectives were used as a framework for the current United States program regarding STDs, which consists of the following components:

1. Health education and promotion.
2. Disease detection through testing and other means.
3. Appropriate treatment.
4. Contact tracing and patient counseling.
5. Clinical services.

6. Training.

7. Research.

C. The Challenge of AIDS Control

It might seem reasonable to extend the experience in preventing the spread of other STD infections to AIDS. The objectives established by WHO/PAHO and the components of the current national STD program are certainly applicable to AIDS. However, AIDS presents a much different social problem than other STD infections. Since there is no cure for AIDS and no protection beyond avoiding or making safer intimate contact with infected individuals, those infected with the virus must be sexually isolated from uninfected persons. A condom barrier offers some but not complete protection. Avoidance of sexual contact and use of shared needles are the only sure protections.

Further, the stigma that accompanies a diagnosis of AIDS, based on fear and society's attitude toward IV drug abusers and homosexuals, presents a factor beyond the control of the infected individual or medicine. An HIV-seropositive individual who might live five years or much longer with no overt health problems, once identified in a community, may be subject to many and varied discriminations--by family and loved ones, by neighbors and friends, by employers and fellow employees, and by other providers of services.

As with prevention and control of all contagious diseases, prevention and control of AIDS involves two, sometimes competing, concerns. First, the person who is afflicted with the disease needs compassionate treatment, and both those who have the disease and those who have been infected with the virus should not be subjected to irrational discrimination based on fear, prejudice or stereotype. Second, and of critical importance, the uninfected must be protected; those individuals who are not infected with the AIDS virus must have every opportunity to avoid transmission of the disease to them.

II. The Need for a National Policy on Aids

Given the growing dimensions of the crisis and given limited national resources, it is imperative that a national policy be developed jointly by the public and private sectors. Such a policy must seek, in a cost-effective way, to achieve fundamental national goals: prevention, treatment, and cure -- and adequate research in all three areas. A coherent national approach to this modern killer is needed: a comprehensive blue print for a national response, not piecemeal solutions. Knowledge of the disease is now more than six years old and the growing magnitude of the problem has been apparent for nearly that long.

Such a national policy must have certain characteristics:

- The policy must be comprehensive, proceeding simultaneously on the fronts of prevention, treatment, and research.
- The policy must be coordinated between public and private sectors and between the different levels of government. A national policy does not necessarily mean a federal policy: there are important roles at all levels of the health care systems and at all levels of government. Nor does it necessarily mean uniformity: on certain issues different approaches should be tried to determine efficacy.
- The policy must be carefully balanced. For example, concern for the person with the disease must be balanced with concern for those who do not have the disease but who may become infected. Similarly, careful consideration must be given to directing scarce resources to increased prevention, even as increasingly large resources are necessarily devoted to research and treatment.
- The policy must be based on scientific information and medical judgments. Although policy choices must inevitably be made, they should be formed on the best available information and on the extensive public health experience in dealing both with AIDS and with other contagious diseases.
- The policy should be nonpartisan. Although it may be tempting to play on fears and prejudices, public figures and officials both inside and outside the health community should avoid exploiting the crisis for partisan political advantage.
- The policy should be capable of continuous review and modification as more and better information becomes available.

RECOMMENDATION 1:

A Commission, modeled after the commission which made recommendations on the problems of Social Security financing in the early 1980s, should be constituted with representatives from the Executive branch of the federal government, the Congress, state and local government, and the private sector and directed to develop a consensus position for consideration by the Congress, the Executive, state and local governments and private associations and institutions. The presidential commission announced, but not yet

appointed, by the Administration could be broadened to implement this recommendation. A high-level body with representatives from the different branches and levels of government, but operating to the side of the more formal political processes, may have the best chance of forging the necessary national consensus which can then become the basis for concerted and coordinated action by both the public and private sectors.

III. The Special Role of Physicians and Other Health Care Counselors

Because there is no cure for AIDS, effective preventive techniques are vital. This involves both those who are infected and those who are not. Those who are infected must be identified so that they will not unknowingly transmit the disease to others. Many who are not infected will need to change their behavior substantially to minimize their risk of infection by the AIDS virus.

The key to changed behavior is public education coupled with counseling which must be given by physicians and other health care counselors.

A. Public Awareness

The public is well aware of AIDS in a general sense. The attention of the media has been intensively focused on the disease. Translating general awareness into modifications of behavior is the challenge.

The groups that are most at risk for AIDS, e.g., IV drug abusers, homosexuals, bisexuals, and prostitutes, have reason to know they are at risk. Their contacts, however, may not know they are at risk and hence spouses, unborn babies, and premarital and extramarital sexual partners may become infected. Education and counseling aimed at the high-risk groups must be the first priority. The education should urge immediate counseling with a physician or other health care counselor about the risk of AIDS, the uses of antibody testing and preventive measures.

Also, it must be recognized that persons in these groups may not respond to education and counseling and, when they do not, more aggressive programs--such as expanded methadone maintenance programs or penalties for knowingly exposing others--must be considered.

Education aimed at the more general population is difficult for at least two reasons. First, reaching all Americans with an effective message can be expensive and not all people respond in the same way or to the same method of learning. Messages must therefore be tailored to the target audience in question. Second, preventive messages must necessarily deal with controversial subject matter. Widespread use of the electronic media -- especially television --

appears to be the most effective way to reach the general public. Accordingly, public service advertising on the electronic media must be greatly increased and these announcements must be shown at times and in places where they will be viewed by those who need the message most.

The AMA will continue its efforts to place its own public service ads on national television. AMA's Tony Danza public service advertisement (PSA) directed at teenagers about abstinence and condoms, and other PSAs which the networks have agreed to use, are significant first steps. But, more must be done and it must be nationally coordinated.

RECOMMENDATION 2:

The communications industry must develop voluntary guidelines for public service advertising regarding AIDS in consultation with the health care community and government officials. The AMA intends to be a catalyst in this effort to immediately bring the communications and health care communities together.

B. Counseling--And Educating Counselors

Perhaps the greatest need at the present time is effective counseling of both low-risk and high-risk populations by physicians or other health care counselors. A massive education effort for physicians and other counselors is necessary as a first step. Complete and accurate information on the disease, the modes of transmission, the appropriate application of antibody testing, and effective ways to change behavior must be understood by counselors if it is to be properly communicated to patients. In conjunction with face-to-face counseling, printed materials--like the Surgeon General's recent 36-page report on AIDS--should be widely disseminated.

Even more challenging than preparing physicians and others for generic counseling on AIDS is preparing these counselors to assist those who test positive and are infected with the virus. It is at that time that a change of behavior on the part of the person infected is most critical, and it is then that the most sophisticated counseling is required due to the emotional impact of the test results. There is no higher prevention priority than ensuring that the community of individuals who provide health care counseling be given adequate tools to be effective. And the AMA, as the largest organization of physicians in the world, must take a leading role in this undertaking.

RECOMMENDATION 3:

A conference should be immediately held between the AMA, other

physician organizations and public health officials at all levels of government to determine:

1. The types of education and training that are necessary for effective counseling.
2. The people in the health care community who should receive this education and training.
3. The current resources available for such education and training.
4. Recommendations for providing additional resources, including consideration of the respective roles of medical associations and government at all levels.
5. Recommendations on how to update information continually as new scientific data are developed.
6. Recommendations as to alternative measures to prevent the spread of AIDS where education and counseling are not likely to be effective, particularly among IV drug users, through such programs as expanded methadone maintenance.

The AMA will promptly and widely report on the conference findings and assist in the implementation of the conference recommendations.

C. Voluntary and Mandatory Testing

Knowledge that a person is infected with the AIDS virus can be the crucial predicate to changing behavior. Thus, testing for an antibody to the AIDS virus, when used in conjunction with appropriate counseling (and when offered in the context of appropriate anti-discrimination and confidentiality protections discussed below), serves the important public health purpose of providing impetus for behavior changes that minimize the risk of transmitting the AIDS virus.

Clearly, the need for HIV-antibody testing has expanded beyond its original purpose, the screening of blood donors. Guidelines for the appropriate use of HIV-antibody testing must center on the following justifications:

1. To identify infected persons and to offer treatment where possible and to protect uninfected third parties.
2. To offer education and counseling that would modify high risk behavior.

3. To solicit patient cooperation for locating and referring sex partners.
4. To obtain broadened epidemiological statistics on the prevalence of HIV infection in the population.

In addition, in considering the merits of voluntary versus mandatory testing, these facts about AIDS must be kept in mind:

1. AIDS is caused by an infectious agent, and therefore is an infectious disease. Appropriate precautions, procedures, and policies should be applied to protect the community from the spread of the disease.
2. The extent to which the AIDS virus already has spread into the general population is not completely understood. Current projections are based on a number of unverified assumptions.
3. The transmission of the AIDS virus does not occur through casual contacts. Sexual contact, septic intravenous equipment, and the administration of infected blood and blood products are the main modes of transmission.
4. Heterosexual transmission of the AIDS virus, especially from males to females, does occur.
5. Seropositive pregnant females will transmit the virus to their babies in a high percentage of cases.
6. Health care workers, especially those who perform invasive surgical procedures, and emergency room and laboratory personnel, are at some risk when caring for AIDS patients.
7. No patient with a clinical case of AIDS has survived the disease. The disease has been uniformly fatal.
8. The disease, not its victims, is the threat from which society must be protected.
9. The confidentiality of the doctor-patient relationship is vitally important but not absolute.
10. Physicians have an ethical and professional obligation to behave in a scientifically responsible manner.

All of these considerations guided the Board of Trustees as it considered the issues that have been raised by the wide variety of proposals for HIV-antibody testing that are being discussed in society.

General Conclusions

Except for individuals in the limited categories listed in Recommendation 5 below (blood, organ and semen donors, immigrants, military personnel, prison inmates) with regard to whom testing serves well-established and well-accepted protection goals, mandatory national testing should not, at present, be broadly extended.

Military personnel have traditionally been subject to mandatory immunizations and our defense forces, of course, must be as strong as possible. Prison inmates, because they are confined and have a higher incidence of high-risk individuals than the general population, require special protection. Immigrants should be tested so that we can focus on the AIDS problem already here, and the nation certainly has the right to bar entrants with communicable diseases. The need to test donors of blood, organs and semen has never been questioned.

Public health authorities have advanced a plausible premise for their opposition to mandatory testing of homosexuals and drug abusers: such testing will only drive people underground and away from the health care system. Public health authorities also have advanced a premise for not requiring mandatory testing of large segments of the general population, such as all those seeking marriage licenses or all those admitted to hospitals: such testing in low prevalence populations would result in a high proportion of false positives, and would not be cost-effective, given the demand for voluntary testing and the shortage of testing and counseling resources for those who want them voluntarily or who will want them following effective public awareness campaigns.

Until those premises are shown by superior studies to be incorrect, a policy regarding mandatory testing which has been rejected by the vast majority of public health officials, including the Centers for Disease Control and the Surgeon General, cannot be recommended.

But certain high risk groups should be regularly tested, with a right to informed consent and to refuse the test. Those groups are defined in Recommendation 6.

In addition, physicians and other hospital personnel involved in invasive surgical procedures who necessarily and unavoidably come in contact with the blood of patients, need to be aware of their risks. Limited regular testing of patients will assure that the CDC

guidelines for the protection of hospital personnel are followed rigorously and will further assure that all patients receive prompt and full treatment. The Board emphasizes here that physicians have a long and honored tradition of tending to patients afflicted with infectious diseases with compassion and courage. That tradition must and will be continued throughout the AIDS epidemic.

Because the risk to health care personnel will be slight in most areas, any effort at mandatory testing of certain kinds of patients should be instituted after voluntary testing has failed and where a variety of factors, e.g. the costs and availability of proper testing and counseling as measured against the risk presented by the relative presence of a high risk patient population, weigh in favor of mandatory testing.

The AMA does not believe it appropriate at this time to extend regularly offered testing to persons other than those listed, e.g., recommended testing should not be extended to all individuals anywhere who are considering marriage or to all persons in hospitals. Decisions about whether there should be generally recommended testing to other types of individuals should, at this time, be left to the decision of the local community depending on its own circumstances and the judgments of its own public health officials.

At present, each case of AIDS must be reported by the individual physician to state public health authorities either by name or identifier. Anonymous, or if carefully implemented, confidential reporting should also be extended to all confirmed instances of persons infected with AIDS virus but not afflicted with ARC or AIDS. Individuals who are seropositive for the HIV antibody are infected with the virus and can spread the disease as certainly as those with symptoms of AIDS. A sound epidemiologic understanding of the potential impact of AIDS on society requires the reporting of those who are confirmed as testing positive for the antibody to the AIDS virus.

Testing Recommendations

RECOMMENDATION 4:

Tests for the AIDS virus should be readily available to all who wish to be tested. The tests should be routinely subsidized for individuals who cannot afford to pay the cost of their test.

RECOMMENDATION 5:

Testing for the AIDS virus should be mandatory for donors of blood and blood fractions, organs and other tissues intended for transplantation in the U.S. or abroad, for donors of semen or ova collected for artificial insemination or invitro fertilization, for

immigrants to the United States, for inmates in federal and state prisons and for military personnel.

RECOMMENDATION 6:

Voluntary testing should be regularly provided for the following types of individuals who give an informed consent:

1. Patients at sexually transmitted disease clinics.
2. Patients at drug abuse clinics.
3. Pregnant women in high risk areas in the first trimester of pregnancy.
4. Individuals who are from areas with a high incidence of AIDS or who engage in high-risk behavior seeking family planning services.
5. Patients who are from areas with a high incidence of AIDS or who engage in high risk behavior requiring surgical or other invasive procedures. If the voluntary policy is not sufficiently accepted, the hospital and medical staff should consider a mandatory program for the institution.

RECOMMENDATION 7:

As a matter of medical judgment, physicians should encourage voluntary HIV testing for individuals whose history or clinical status warrant this measure.

RECOMMENDATION 8:

Individuals who are found to be seropositive for the AIDS virus should be reported to appropriate public health officials on an anonymous or confidential basis with enough information to be epidemiologically significant.

RECOMMENDATION 9:

Physicians should counsel patients before tests for AIDS to educate them about effective behaviors to avoid the risk of AIDS for themselves and others. In public screening programs, counseling may be done in whatever form is appropriate given the resources and personnel available as long as effective counseling is provided.

RECOMMENDATION 10:

Phys'cians should counsel their patients who are found to be seropositive regarding (a) responsible behavior to prevent the spread of the disease, (b) strategies for health protection with a

compromised immune system, and (c) the necessity of alerting sexual contacts, past (5-10 years) and present, regarding their possible infection by the AIDS virus. Long-term emotional support should be provided or arranged for seropositive individuals.

RECOMMENDATION 11:

Patients should knowingly and willingly give consent before a voluntary test is conducted.

IV. Resources

Only recently has Congress and the Administration begun to seriously consider the vast resources needed to deal effectively with AIDS. Federal funding for 1988 is expected to reach \$1 billion. But that amount will not be enough. The AMA endorses the bill introduced by Congressman Waxman to increase resources for testing and counseling.

Testing for the HIV virus in America will require substantially more resources than are currently being made available. Trained counselors, materials for counseling, and research on effective counseling approaches, for the variety of population groups that need these services, are urgently required. Also, dependable testing facilities with sufficient capacity to respond to the epidemic are needed now. In addition, funds for research and care must be increased to fully exploit the nation's capacity to respond effectively to this crisis.

The key premise of a prevention strategy, when there is no vaccine, is behavioral change on the part of those infected and those at risk of infection by AIDS virus. It is therefore crucial that there be immediate and systematic studies conducted of how behavior of affected groups may have changed in recent years, and if possible, what factors caused the changes. Most particularly, it is necessary to study and evaluate the types of counseling that have been effective so that the techniques may be replicated widely. There can be little question that in a free society suasion and voluntary change, if effective, are far preferable to compulsion.

RECOMMENDATION 12:

Public funding must be provided in an amount sufficient (1) to promptly and efficiently counsel and test for AIDS (2) to conduct the research necessary to find a cure and develop an effective vaccine, (3) to perform studies to evaluate the efficiency of counseling and education programs on changing behavior and (4) to assist in the care of AIDS patients who cannot afford proper care or who cannot find appropriate facilities for treatment and care.

V. Protection Against Discrimination

A. Anti-Discrimination

The AMA believes strongly that AIDS victims and those who test positively for the antibody to the AIDS virus should not be treated unfairly or suffer from arbitrary or irrational discrimination in their daily lives.

RECOMMENDATION 13:

Anti-discrimination laws must be clarified or amended to cover those who test positive for the antibodies to the AIDS virus.

B. Confidentiality

The ability of the health care community to maintain the confidentiality of patient information and restrict its use to only those purposes essential for maintenance of health is, like clarification of anti-discrimination laws, vital to an effective program of preventing and controlling AIDS. Even if anti-discrimination laws were completely effective, which unfortunately is not likely, persons who test positive (such as those with ARC or AIDS), will suffer stigma. Thus, confidentiality is crucial.

RECOMMENDATION 14:

Model confidentiality laws must be drafted which can be adopted at all levels of government to encourage as much uniformity as possible in protecting the identity of AIDS patients and carriers, except where the public health requires otherwise.

V. Questions for the Future

As the national debate on prevention and control of AIDS continues, other important issues will need to be addressed.

A. Research and Data

There is an urgent and critical need for more scientifically sound data on the prevalence and spread of virus in the general population. At the present time only those cases that meet the current CDC surveillance definition of AIDS are reported to that institution. Since AIDS is the terminal and fatal stage of HIV-infection, it represents only the tip of the huge HIV-infection iceberg. There are protean manifestations of HIV-infection ranging from infected asymptomatic to full-blown AIDS. How large the base of that iceberg really is—that is, how many people are actually infected—can only be estimated from the number of reported AIDS cases. That has been done by using a multiple (50 to 100 times the

number of AIDS cases) that has been extracted largely from surveys done in high-prevalence areas. Yet this same multiple has been used to estimate the number of current and potential HIV-infected persons in low-prevalence areas and for that matter the entire country and even the world. The CDC itself is unsure about the accuracy of its estimates. Yet if economic and medical plans are to be made for the future, reliable projections must be available. How sufficient or exaggerated these plans may be depends upon the accuracy of current and future estimates of HIV-infected persons, particularly as to the extent of its spread into the low-risk heterosexual population.

Not only are accurate estimates of HIV-infected persons needed, but so too are reliable data on the rate conversion of asymptomatic seropositive persons to clinical illness, including AIDS, that requires increased medical care. This information is important for the formulation of plans for the future cases of potentially hospitalizable patients and the economic consideration thereof. HIV-infection has protean manifestations and death can result not only from AIDS itself, but from severe ARC or progressive CNS disease as well. In order to obtain accurate information in HIV infected persons on the rate of conversion from asymptomatic to clinically severe illness, baseline data on their serologic status must be obtained as early as possible--not after clinically manifest disease is present. The presence of HIV antibodies indicates not only current infection with the virus, but also that the patient is potentially capable of transmitting the disease. This follows from the fact that HIV integrates its genome into the host cell genome with the result that once infected, the patient remains infected for life and is, therefore, capable of life-long transmission of the agent. The earlier the infected person is detected, the earlier he or she may be advised of this contagious state and counseled on how to avoid further transmission of this lethal virus.

RECOMMENDATION 15:

Consistent with the proposal by the Secretary of Health and Human Services, a national study in various areas of the country must be immediately undertaken to determine the prevalence and conversion rate of the virus in the United States population, and the study must be repeated at appropriate intervals to gauge the spread of the disease.

B. Warning to Third Parties

One of the more difficult issues for society is how to warn unsuspecting spouses or sexual partners of persons who test HIV positive. Such a warning would allow the third party to practice "safer" sex or to abstain from sexual relations with the infected person altogether. Given the life-or-death consequences, the unsuspecting third party should, as a general matter, be warned

because there is no cure and because it may not be responsible to rely solely on the infected person to provide a suitable warning.

Physicians who have reason to believe that there is an unsuspecting sexual partner of an infected individual should be encouraged to inform public health authorities. The duty to warn the unsuspecting sexual partner should then reside in the public health authorities as well as the infected person and not in the physician to the infected person.

The AMA believes that mechanisms, analogous to those used by public health authorities to warn sexual partners about other sexually transmitted diseases, should be put in place to warn unsuspecting third parties about an infected sexual partner. Such warning may be appropriate whether the infected person is bisexual, heterosexual or homosexual.

RECOMMENDATION 16:

Specific statutes must be drafted which, while protecting to the greatest extent possible the confidentiality of patient information, (a) provide a method for warning unsuspecting sexual partners, (b) protect physicians from liability for failure to warn the unsuspecting third party but (c) establish clear standards for when a physician should inform the public health authorities, and (d) provide clear guidelines for public health authorities who need to trace the unsuspecting sexual partners of the infected person.

C. Sanctions for Reckless Disregard for the Safety of Others

A related question which must be explored is whether an infected person, who knows he or she is infected and who knowingly fails to warn a sexual partner of the infection, should be subject not just to tort suits, but to a proceeding brought by state authorities to sanction the individual.

RECOMMENDATION 17:

Given the risk of infection being transmitted sexually, and given the dire potential consequences of transmission, serious consideration should be given to sanctions, at least in circumstances where an unsuspecting sexual partner subsequently finds out about a partner's infection and brings a complaint to the attention of authorities. Pre-emptive sanctions are not being endorsed by this recommendation.

CONCLUSION

The Board intends to review its evaluation of the developing AIDS epidemic on a constant basis. Modifications of the AMA's positions will be made as the situation warrants.

Games of the “Medical Revolution”

continued from page 20

her insurance company preadmission department is in Pittsburgh and they care about her so much they have added a new “benefit” to her policy and they want to see if what you’re doing is right.

Now you call up. The line’s busy for the first 15 minutes. Mrs. Jones is starting to look pale, but first things first. You finally get through to the “authorities.” You tell the nurse on the other side of the phone about Mrs. Jones. She looks up in her “cookbook” to see if hospitalization is required. No medical education but that cookbook, mind you, and that’s why this game is so much fun.

Later, after you discharge Mrs. Jones, the insurance company sends auditors to mull over your chart. They see you prescribed a drug that wasn’t necessary (According to them, you see they have that “medical education” which gives them license to do these things). They aren’t going to pay for it either.

Next, you write a prescription for Mrs. Smith and she’s off to the local drug store. The pharmacist thinks that your choice of drugs stinks, and he tells Mrs. Smith. The drug you gave her has side effects — did she know that? And when your prescription runs out, he keeps filling it (no matter that you retired four years ago).

Finally, you get a call that an insurance company auditor has just denied your admission of Mr. Brown back in 1985. They reviewed his records and he didn’t fulfill their criteria (another cookbook).

Well, as you can see, anyone can “play doctor” these days. Mention liability though and they all run for cover.

Papershuffler: This is a game that’s become the rage in modern medicine. Any number can play and the more the merrier. The main participants are physicians and insurance company clerks. The object of this game is to see who can shuffle paper faster. First the physician submits a claim; the insurance company clerk sends it back — Code 9Z1, Resubmit — the physician returns it — the insurance company clerk returns it for a itemized statement — the physician returns it — the insurance company clerk returns it asking for a letter describing what was done and why.

The game continues until either the physician gives up or the insurance company clerk pays the claim. Great game for those with bureaucratic tendencies.

Take a Seat, Any Seat: This is a variation on the old party game, musical chairs. This one’s played at the nurse’s station when you’re making rounds. You have a chart and need to find a chair to sit down in so you can write your orders. You look around. The ward clerk has her chair, the nurse has her chair, the dietician has her chair, the pharmacy tech has his chair, the respiratory therapist has her chair, the Blue Cross

auditor has her chair, the discharge planner has her chair, the Medicare auditor has her chair, the quality assurance auditor has her chair — no more chairs. Give up; you lost. After all, the physician isn’t all that important. Try again at the next floor.

Shellcaid Game: This is an old carny favorite that has been updated by the State Medicaid Agency. First, the state tells its underprivileged citizens that they have health insurance. They go to their doctor for care. The doctor submits a claim. Now the fun begins! Watch those shells. Under which shell is the payment for this claim. No, sorry Sonny, you submitted your claim on the wrong claim form. Wrong again, you forgot to get this one signed. Wrong again, you forgot item 6C. Too bad, Sonny, the game’s over, your time limit has run out. Feel like a sucker?

Medicare Bill Paying Game: This is a fun game for those that love to save money! Get out those bills! First, the phone bill. Think South Central Bell charged you too much? \$350 sounds pretty steep. Well, what do you think is fair? \$175? Now write a check for \$140. That’s right, \$140 — you know, 80% of your approved amount. Send it off. You just paid your phone bill and saved \$210!! What a great game! Since 1982, this game has been updated so that the same approved amount is used no matter what inflation does. This saves you even more money!

Capitation Game: This game is really fun. First you decide if you want to be an insurance company executive or the physician. The insurance company executive sells a policy to a group for a set amount and makes the physician take the risk! Unbelievable you say! Just wait, the fun is just beginning! Now the insurance exec skims off 15% for himself, moves to the center of the board marked “U.S. Virgin Islands” and leaves you back in the states doing the work.

You move around and around the board doing your job, taking care of the sick. When the funds run out, never mind, just keep on going. This is a fun game. Capitation is a great idea — isn’t that the way we pay the electric bill and buy groceries?

Risk Free: Now this is a new twist. Everyone wants to make things safe. If there’s a risk, let’s get rid of it. We do this by levying a tax called Liability Suits and Hefty Jury Awards. If we can’t get rid of the risk, such as a cliff, let’s put up signs saying “Don’t jump off this cliff; you might get hurt!” (Actually happened! How did our ancestors ever get along without this?) Or signs that say “Taking this CAT scan might cause you to lose your mental telepathy!” This is a fun and expensive game whose outcome is unknown at this time.

Baby Lottery: This is not gambling for children. Baby lottery is a way to get rich quick by having a baby. Having a baby? You always thought it cost a lot of money to have and raise a baby — how can you get rich quick? Well, if you’re lucky, something will

go wrong and you can sue your obstetrician. Whatever it is, blame him because he's the one with the lottery reserves (liability insurance).

Entry into this game doesn't take skill and is quite enjoyable. The cost to play this game is high for the obstetrician and has forced many of them to cash in their chips and fold.

You Can't Do That: This is a game by DRG Industries that bridles the brazen audacity of senior citizens. Some of these older folks think they can come in the hospital for one problem and have another problem taken care of. For example, one man thought he could be admitted for a hemorrhoidectomy and have a heart attack during the same admission. He even wanted a pacemaker! Well, the folks at DRG Industries will let him know that he can't. He will just have to wait to have his heart attack during another admission (preferably by appointment and preapproved). This game is teaching physicians to ignore their patients' complaints and have tunnel vision: "Mrs. Jones, ignore that cough, we're concentrating on your gallbladder."

Of course, when the attorneys start snooping around, the physician finds out that DRG Industries makes the game and the rules but doesn't have anything to do with the outcome.

Like It or Lump It: This is a new game from DRG Industries being readied for market that will add new fun to hospital medicine. This game will lump payment for physicians in with hospital payments. The government is hoping that eventually all payments can be made to one person for everyone in the country. This one person can then pay everyone else. This will simplify things like the new W-4 form has simplified withholding. So far this game has met with a poor response.

Take It or Leave It: This is a new game that the insurance industry loves. You submit a claim and they pay part of it. They state that part of your bill was not approved for various reasons. Or they tell the patient that you've been paid enough and if you try to get more they'll go to court on their behalf. I wonder if they would be interested in doing this for our legal and accounting fees?


Sign For a Discount: This is a new game that allows participation nearly every week. You receive a contract in the mail that asks you to sign up to care for a group and for this privilege they ask you for a discount. Sometimes they even ask for payment for this privilege. One even asked for payment, a discount, and then bankrupted on outstanding accounts. What fun!

Paper Treatment: Nobody treats patients anymore in the hospital. They treat paper. Nurses don't have time for "TLC," they're too busy charting. This game provides you with a box of paper so you can simulate treating hospitalized patients.

Alliance: This is a fun game for those that love strategy. Who are your friends and who are your adversaries? This game reflects changing alliances in a changing medical environment. Remember the hospital that was trying to develop a new program you saw as a threat? You marshalled your resources and enlisted other hospitals to launch an ad campaign to block it. Now that you have your own HMO, however, you see that this program makes your HMO complete. So you enlist this hospital and now you're good buddies. That's the fun and irony of "Alliance."

Phone Flea: This is a game for those that love details. It is brought to you by the makers of "papershuffler" and "take it or leave it." And this game isn't just for internists (sometimes referred to as fleas by our "if-in-doubt,-cut-it-out" colleagues. The game requires a phone and a lot of patients/patience.

Any test you want to order requires preapproval from the company. If you want a CT scan, give them a call and ask. If you want an upper G.I., give them a ring. A chem profile? Reach out and touch someone. A stool guaiac? Dial it up, but make sure you don't use the gloved hand and mess up your buttons. □

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CASE REPORT:

Non-Hodgkin's Lymphoma Presenting Initially As a Sleep-Apnea Syndrome

Charles M. Carr, M.D.*

Introduction

Eighty percent of adult patients with lymphomas present to their physicians with superficial adenopathy. The enlarged lymph nodes are painless and the patients are usually asymptomatic, although 20% of non-Hodgkin's lymphomas will have systemic signs, fever being the most common. Pressure symptoms and extranodal manifestations are much less common.¹⁻³ Primary lymphoma of the central nervous system (CNS) may present with somnolence but will usually have other CNS associated signs and symptoms.⁴ The presentation of a non-Hodgkin's lymphoma with somnolence, and the absence of adenopathy, seems to be distinctly unusual.

History

A 54 year old black male presented with a complaint of excessive daytime sleepiness. Although he had a

long history of obesity, nocturnal snoring, and daytime somnolence, he was able to manage his affairs until he was placed on propranolol for control of his hypertension. He noted a steady progression of his somnolence over a one year interval so that he now fell asleep while engaged in conversation and while eating. He also complained of headaches, low back pain, sore tongue, nasal stuffiness, and a recent decrease in auditory acuity. He did not complain of fever, night sweats, weight loss, or pruritus.

Physical Examination

The patient was very obese, slow, and sleepy. His speech was slurred. When not stimulated, he dozed and saliva drooled from his lower lip to his shirt front. He had a trace of edema in the lower legs and no deep tendon reflexes. The thyroid was not enlarged and there were no enlarged lymph nodes. The blood pressure, heart, lungs, and abdomen were normal.

The peripheral blood smear and hematocrit were normal. The metabolic profile was normal except for

*Associate Professor of Family Medicine, UAB Family Medicine Center, Selma, Alabama. Requests for reprints should be addressed to: Charles M. Carr, M.D., UAB, Selma Family Medicine Center, 429 Lauderdale Street, Selma, Alabama, 36701.

a minimal elevation of the total protein (8.2 g/dl) and alkaline phosphatase (118 u/ml). Thyroid function was normal.

Outpatient Course

The patient's propranolol dosage was titrated to zero to remove CNS sedation. One month later he returned with his mother who stated that he could never stay awake and that his speech had deteriorated so badly that only she could understand him. He looked ill and had bilateral preauricular and cervical lymphadenopathy.

Hospital Studies

The patient's heart was enlarged on chest X-ray. Soft tissue X-rays of the neck were consistent with adenopathy. Tomograms of the larynx and a cranial CT scan were normal. There was no esophageal obstruction on barium swallow. Pulmonary function studies were markedly impaired: FVC 1.47 liters, FEV₁ 1.14 L/min (both 32% of normal); MVV 32 L/min (18% of normal); FEV₁/FVC 77% (normal). There was very little change after bronchodilator: FVC 1.84 liters (40%), FEV₁ 1.53 L/min (43%), MVV 40 L/min (27%), FEV₁/FVC 83%. Arterial blood gases were abnormal: pH 7.38, PaCO₂ 52 mmHg, PaO₂ 65 mmHg. The EEG demonstrated drowsing episodes at 20 minute intervals without the acute onset of recurring eye movement artifact (a characteristic of narcolepsy).

At laryngoscopy he had excessively redundant mucosal folds. The biopsy was suggestive of a lymphoma. Biopsy cultures were negative. He was transferred to the University of Alabama in Birmingham (UAB) for staging and treatment.

UAB Studies

There were no masses seen on CAT scans of the chest, abdomen, and pelvis. Bone marrow aspiration was normocellular with no sign of lymphoma. Anterior cervical node biopsy showed diffuse large cell (histiocytic) lymphoma.

Treatment and Response

The patient was treated with cyclophosphamide 750 mg/m², adriamycin 60 mg/m², and vincristine 2 mg on day one, and prednisone 100 mg p.o. q.d. x 5 days (CHOP). Fifteen days later his sleepiness, nasal stuffiness, and difficulty hearing had resolved. A week later he had no palpable nodes. The CHOP protocol put him into complete remission.

His post treatment PFT showed complete resolution of his obstructive pulmonary disease: FVC 2.9 liters (69%), FEV₁ 2.6 L/min (80%), FEV₁/FVC 89%.

Discussion

Although non-Hodgkin's lymphoma usually presents with asymptomatic lymphnode enlargement, other presentations can occur. In this case the patient was aware of nearly ten years of daytime somnolence which progressed rapidly over a three month period and was finally accompanied by lymph node enlargement. There was no evidence for central nervous system involvement.

This patient appears to have had a longstanding problem with obstructive sleep apnea characterized by heavy snoring, excessive daytime sleepiness, intellectual and personality changes, and systemic hypertension.⁵ This was tolerated until the closed lymphoid follicles in the corium of the lining epithelium of the nasopharynx began to enlarge. This lymphoid tissue is particularly abundant in Waldeyer's ring and in the tonsil of Gerlach which is on the rim of the eustachian tube. Growth of these tissues can cause hypoacusia, impaired soft palate movement, and mandibular neuralgia (Trotter's clinical triad).⁶

It appears that lymphoid growth in this patient reduced the size of his upper airway and caused an intensification of his sleep apnea syndrome. Because he was obese and had a short, stocky neck, his cervical nodes could not be palpated until they had become quite large, three months after the onset of his severe sleeping problems. Arrest and reduction of his lymphoma by chemotherapy permitted a reversal of his obstructive sleep apnea.

Conclusion

When patients present with sleep disturbances, hypoacusia, nasal congestion, or unexplained maxillofacial and cranial nerve syndromes, lymphomas must be included in the differential diagnosis. □

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Should Patients With Inoperable Localized Brochogenic Carcinoma Receive Aggressive Radiotherapy?

Steven H. Stokes, M.D.*

Allen Latimer, M.D.†

Dale Prophet, M.D.‡

William Kann, M.S.§

All of us who care for cancer patients are aware of the epidemic of Brochogenic Carcinoma. Last year in Alabama lung cancer accounted for 2,500 deaths with cancer of the colon and rectum a distant second with 800 fatalities.¹ Unfortunately the majority of patients with lung cancer are inoperable at diagnosis leaving radiation therapy as the alternative treatment. The long term survival following curative attempts with radiation therapy remains poor (5-15%)^{2, 3, 4} prompting some to suggest limiting treatment only to palliation of specific tumor related symptoms.^{5, 6}

However focusing only on long term survival in a disease with a high incidence of distant metastasis overlooks the importance of controlling the tumor within the chest.

What Kills the Patient with Lung Cancer?

In seeking methods to improve survival we must determine how a lung cancer kills a patient. Cox et

* Director-Department of Radiation Oncology, Southeast Alabama Medical Center, Dothan, Alabama.

† Director-Department of Pulmonary Medicine, Southeast Alabama Medical Center, Dothan, Alabama.

‡ Director-Department of Pulmonary Medicine, Flowers Hospital, Dothan, Alabama.

§ Medical Physicist, Department of Radiation Oncology, Southeast Alabama Medical Center, Dothan, Alabama.

al,⁷ evaluated with autopsy the cause of death in 300 consecutive patients treated with radiation therapy. He detected important differences in the etiology of death according to the histologic subtype. Squamous cell cancer killed primarily by uncontrolled growth within the chest with 70% of patients dying from hemorrhage, obstructive pneumonia or cardiorespiratory failure. Although the majority of patients with Adeno or Large cell carcinoma died of distant metastasis, 40% expired as a result of uncontrolled intra-thoracic disease. This study emphasizes the importance of controlling the tumor within the chest.

Does Aggressive Radiotherapy Improve Local Control?

A concept difficult for some physicians is that although radiation, like surgery, is a localized form of treatment it is not an all or none phenomenon. The surgeon at the time of the operation if possible removes all the cancer. However the Radiation Oncologist can administer a gradation of radiation dosages to the tumor. An accepted fact is that larger tumors require higher doses of irradiation for control.

Several studies have confirmed that higher radiation

doses result in greater tumor control and at least a short term improvement in survival.^{2, 3, 8} Perez et al² noted a progressive reduction in intrathoracic tumor recurrence among 378 patients with increasing doses of radiation being 52%, 41% and 30% for 4000, 5000 and 6000 rad respectively. This increased local control results in an increased survival at 2 years but the 5 year survival remains disappointingly at less than 10%.

TABLE 1^a
Actuarial Survival by Dose

<i>Doses in rad</i>	<i>2 year</i>	<i>5 year</i>
6000	30%	7.5%
5-6000	20%	
45-5000	10%	0%
4500	0%	

One specific factor predicting long term survival is whether the patient experiences a complete response to treatment, generally defined as greater than 50% regression. Perez⁹ in a recent update noted that survival for patients experiencing a complete response to treatment was 25% at 2 years and 15% at 5 years. For

those with less than complete response, the survival was 10% at 2 years with none surviving for 5 years. This emphasized that prolonged survival requires aggressive irradiation in doses adequate to achieve substantial regression of the tumor. However the Radiation Oncologist is technically limited in the amount of external irradiation which can be given safely. One solution for tumors occurring within the bronchus is to place (via bronchoscopy) a radioactive wire adjacent to the tumor as a localized boost (Intrabronchial Irradiation).

Intrabronchial Irradiation

Treatment of intrabronchial tumors by precise placement of radioactive wire was the outgrowth of palliative attempts for patients relapsing or failing to respond to external irradiation. These patients experience hemoptysis, obstructive pneumonia and hypoxia. Efforts to relieve these symptoms have included laser photo resection,¹⁰ intrabronchial irradiation,^{11, 12} or the two in combination.¹³ The two appear equally effective in opening the airway and relieving obstructive symptoms in greater than 90% of patients. One disadvantage of laser resection is the requirement for general anes-

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thetia in some cases¹⁰ and several days hospitalization.¹³ Intrabronchial irradiation is performed as an outpatient procedure requiring 2½-3 hours with little morbidity other than that experienced with routine bronchoscopy.

The procedure entails the Bronchoscopist placing a 4 mm after loading plastic catheter through the bronchoscope past the area of obstruction. The bronchoscope is then withdrawn leaving the catheter in place which is then secured with tape. The Radiation Oncologist then inserts inert seeds into the catheter and a chest x-ray is obtained to verify accurate placement of the seeds. Any adjustments in catheter placement are made and the inert seeds are replaced by radioactive seeds covering 8 cm in length which will deliver 300 rad per hour to a volume 2 cm in diameter. Following current recommendations we have been delivering 500-600 rad per treatment session. The procedure is then repeated on a weekly basis until there is no residual tumor or a maximum of four treatments have been given. We have now treated seven (7) patients with 15 procedures without complications. Similar to other institutions we are experiencing excellent tumor clearance and have successfully relieved obstructive symptoms in all patients to date.

Conclusions

Patients with a good performance status who have localized unresectable lung carcinoma benefit from intrathoracic control of their disease. Aggressive external irradiation in excess of 6000 rad in 6 weeks results in improved local control and prolongation of symptom free survival although the 5 year survival remains poor. Patients presenting with hypoxia, postobstructive pneumonia or intractable cough as a result of intrabronchial tumor benefit from immediate aggressive

local therapy directed to relieving their bronchial obstruction. Although laser photo resection is an alternative, we feel intrabronchial irradiation is the treatment of choice due to patient comfort and convenience. We attempt to induce complete regression and if possible complete disappearance of the intrathoracic disease in all patients by combining aggressive external and intrabronchial irradiation as necessary. It is unclear whether this will translate into an improved long term survival in view of the high incidence of distant metastasis although we are pleased with the improved quality of life our patients are experiencing. □

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Note:—Culture and susceptibility tests should be initiated prior to and during therapy. Renal function studies should be performed when indicated.
Contraindication: Keflet is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

Warnings: BEFORE CEPHALEXIN THERAPY IS INSTITUTED, CAREFUL INQUIRY SHOULD BE MADE CONCERNING PREVIOUS HYPERSENSITIVITY REACTIONS TO CEPHALOSPORINS AND PENICILLIN. CEPHALOSPORIN C DERIVATIVES SHOULD BE GIVEN CAUTIOUSLY TO PENICILLIN-SENSITIVE PATIENTS.

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There is some clinical and laboratory evidence of partial cross allergenicity of the penicillins and the cephalosporins. Patients have been reported to have had severe reactions (including anaphylaxis) to both drugs.

Any patient who has demonstrated some form of allergy, particularly to drugs, should receive antibiotics cautiously. No exception should be made with regard to Keflet.

Pseudomembranous colitis has been reported with virtually all broad spectrum antibiotics (including macrolides, semisynthetic penicillins, and cephalosporins), therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with the use of antibiotics. Such colitis may range in severity from mild to life-threatening.

Treatment with broad spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis.

Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone. In moderate to severe cases, management should include sigmoidoscopy, appropriate bacteriologic studies, and fluid, electrolyte, and protein supplementation. When the colitis does not improve after the drug has been discontinued, or when it is severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile*. Other causes of colitis should be ruled out.

Usage in Pregnancy:—Safety of this product for use during pregnancy has not been established.

Precautions: *General:*—Patients should be followed carefully so that any side effects or unusual manifestations of drug idiosyncrasy may be detected. If an allergic reaction to Keflet occurs, the drug should be discontinued and the patient treated with the usual agents (eg, epinephrine or other pressor amines, antihistamines, or corticosteroids).

Prolonged use of Keflet may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics. In hematologic studies or in transfusion cross matching procedures when antiglobulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug.

Keflet should be administered with caution in the presence of markedly impaired renal function. Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended.

Indicated surgical procedures should be performed in conjunction with antibiotic therapy.

As a result of administration of Keflet, a false positive reaction for glucose in the urine may occur. This has been observed with Benedict's and Fehling's solutions and also with Clinestix[®] tablets but not with Tes-Tape[®] (Glucose Enzymatic Test Strip, USP, Lilly).

Broad spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Usage in Pregnancy:—*Pregnancy Category B*—The daily oral administration of cephalexin to rats in doses of 250 or 500 mg/kg prior to and during pregnancy, or to rats and mice during the period of organogenesis only, had no adverse effect on fertility, fetal viability, fetal weight, or litter size. Note that the safety of cephalexin during pregnancy in humans has not been established.

Cephalexin showed no enhanced toxicity in weanling and newborn rats as compared with adult animals. Nevertheless, because the studies in humans cannot rule out the possibility of harm, Keflet should be used during pregnancy only if clearly needed.

Nursing Mothers:—The excretion of cephalexin in the milk increased up to 4 hours after a 500 mg dose, the drug reached a maximum level of 4 µg/mL, then decreased gradually, and had disappeared 8 hours after administration. Caution should be exercised when Keflet is administered to a nursing woman.

Adverse Reactions: *Gastrointestinal:*—Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely. The most frequent side effect has been diarrhea. It was very rarely severe enough to warrant cessation of therapy. Dyspepsia and abdominal pain have also occurred. As with some penicillins and some other cephalosporins, transient hepatitis and cholestatic jaundice have been reported rarely.

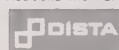
Hypersensitivity:—Allergic reactions in the form of rash, urticaria, angioedema, and, rarely, erythema multiforme, Stevens Johnson Syndrome, or toxic epidermal necrolysis have been observed. These reactions usually subsided upon discontinuation of the drug. Anaphylaxis has also been reported.

Other reactions have included genital and anal pruritus, genital moniliasis, vaginitis and vaginal discharge, dizziness, fatigue, and headache. Eosinophilia, neutropenia, thrombocytopenia, and slight elevations in SGOT and SGPT have been reported.

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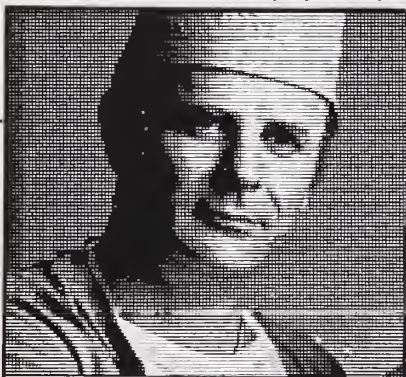
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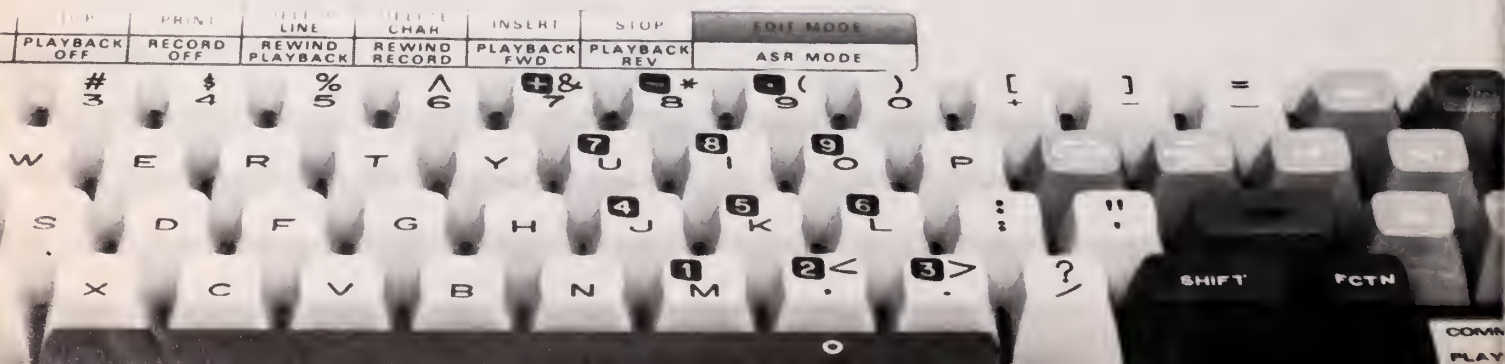
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In keeping with my logo this year, an apple, and my theme, AWARENESS: THE FIRST STEP, I want to make you aware of a situation that is near and dear to my heart. We read in Proverbs that "a word fitly spoken is like apples of gold in pitchers of silver." Fitly spoken words are greatly appreciated in the hospital setting, especially to those who await news of a critically ill spouse, parent or child.

Maintaining a vigil beside the bed of your dying loved one is one of the most dreaded times of your life. We all hope to be spared it. Some never have to be in this position. Others may wait hours, days, weeks or months.

Though sitting beside the bed is terrible, not being allowed to sit there is worse. Critically ill patients are usually in the Intensive Care Unit where they can receive, as the name says, intensive, constant monitored care. Family members are obviously in the way so instead are relegated to the ICU Waiting Room. This is a lonely place.

It is not the lack of people in the room that makes it lonesome. The isolation from your loved one causes the loneliness.

Usually the only thing in common with other waiting people is the knowledge that each has a close family member in ICU. However this tends to draw total strangers together in a unique way. Information is exchanged concerning patient histories and present conditions. The doctors and the hospital are usually discussed as well. Tips on hospital rules, food and parking are also frequent topics.

Newcomers to the waiting room are quickly oriented to the routine that revolves around visiting hours. Hospital volunteers frequently act as hostesses, making coffee and casual conversation as well. They readily answer the pay phones and take messages.

Despite all the efforts to be hospitable to each other, the fact remains — your loved one is in critical condition and you are separated.

Fears multiply as time goes by. The sight of any

hospital uniform is met with the anticipation that maybe there is a message from your patient. You wonder when the doctor might arrive. Should you go to the cafeteria for a meal and risk missing him? Every machine rolled down the hall as well as every code blue heightens your fear. Your nerves are frayed. If only someone would tell you something!

Have you waited in this room? By now you may have suspicioned that I have been there. After a year the memories are still vivid. I have been on both sides of the room: first as a pink lady and then as the daughter of a dying father.

My surgeon-husband was very helpful to me at this time. He could enter the unit at will or even talk to the doctors in the doctors' lounge. I had the advantage over others in the waiting room in that my questions were usually answered and I often felt guilty about that.

I will admit it may be more difficult to communicate with some families. Many ask too many questions or become emotionally upset. Some may not appreciate your efforts. A few may become downright hostile. However most feel they are due a daily update by a doctor on the condition of their patient. After all most of the critically ill are not able to comprehend what the doctor may try to explain to them. Therefore it is very important to brief the family everyday and answer, in laymen's language, their questions. This will help to allay their fears and will do much to enhance your "bedside manner" reputation.

Gold and silver are precious metals treasured by all. Equally valued by the family of the sick are words of comfort and encouragement by the attending physician. □

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See the difference in the first week¹

- Sleep improvement in 74% of patients after first h.s. dose²
- Significantly faster relief—62% of total four-week improvement evident in first week versus 44% with amitriptyline alone¹
- Dramatic first-week reduction in somatic complaints²

% Reduction in Somatic Symptoms²

Vomiting	Nausea	Headache	Anorexia	Constipation
Reduced 90%	Reduced 86%	Reduced 72%	Reduced 62%	Reduced 60%

- Only 1/3 the dropout rate due to side effects of amitriptyline alone, although the incidence of side effects is similar¹

Caution patients about the combined effects of Limbitrol with alcohol or other CNS depressants and about activities requiring complete mental alertness, such as operating machinery or driving a car. In general, limit dosage to the lowest effective amount in elderly patients.

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Protect your decision.
Write "Do not substitute."

In moderate depression and anxiety

Limbitrol[®]

Each tablet contains 5 mg chlordiazepoxide and 12.5 mg amitriptyline (as the hydrochloride salt) ^{IV}

Limbitrol[®] DS

Each tablet contains 10 mg chlordiazepoxide and 25 mg amitriptyline (as the hydrochloride salt) ^{IV}

References: 1. Feighner JP, et al. *Psychopharmacology* 61: 217-225, Mar 22, 1979 2. Data on file, Hoffmann-La Roche Inc., Nutley, NJ

Limbitrol[®] ^{IV} Tranquilizer—Antidepressant

Before prescribing, please consult complete product information, a summary of which follows:

Indications: Relief of moderate to severe depression associated with moderate to severe anxiety since hyperpyretic crises, severe convulsions and deaths have occurred with concomitant use, then initiate cautiously, gradually increasing dosage until optimal response is achieved. Contraindicated during acute recovery phase following myocardial infarction.

Warnings: Use with great care in patients with history of urinary retention or angle-closure glaucoma. Severe constipation may occur in patients taking tricyclic antidepressants and anticholinergic-type drugs. Closely supervise cardiovascular patients (Arrhythmias, sinus tachycardia and prolongation of conduction time reported with use of tricyclic antidepressants, especially high doses. Myocardial infarction and stroke reported with use of this class of drugs.) Caution patients about possible combined effects with alcohol and other CNS depressants and against hazardous occupations requiring complete mental alertness (e.g., operating machinery, driving).

Usage in Pregnancy: Use of minor tranquilizers during the first trimester should almost always be avoided because of increased risk of congenital malformations as suggested in several studies. Consider possibility of pregnancy when instituting therapy; advise patients to discuss therapy if they intend to or do become pregnant.

Since physical and psychological dependence have been reported rarely, use caution in administering Limbitrol to addiction-prone individuals or those who might increase dosage, withdrawal symptoms following discontinuation of either component alone have been reported (nausea, headache and malaise for amitriptyline, symptoms [including convulsions] similar to those of barbiturate withdrawal for chlordiazepoxide).

Precautions: Use with caution in patients with a history of seizures, in hyperthyroid patients or those on thyroid medication, and in patients with impaired renal or hepatic function. Because of the possibility of suicide in depressed patients, do not permit easy access to large quantities in these patients. Periodic liver function tests and blood counts are recommended during prolonged treatment. Amitriptyline component may block action of guanethidine or similar antihypertensives. When tricyclic antidepressants are used concomitantly with cimetidine (Tagamet), clinically significant effects have been reported involving delayed elimination and increasing steady state concentrations of the tricyclic drugs. Concomitant use of Limbitrol with other psychotropic drugs has not been evaluated, sedative effects may be additive. Discontinue several days before surgery. Limit concomitant administration of ECT to essential treatment. See Warnings for precautions about pregnancy. Limbitrol should not be taken during the nursing period. Not recommended in children under 12. In the elderly and debilitated, limit to smallest effective dosage to preclude ataxia, oversedation, confusion or anticholinergic effects.

Adverse Reactions: Most frequently reported are those associated with either component alone: drowsiness, dry mouth, constipation, blurred vision, dizziness and bloating. Less frequently occurring

reactions include vivid dreams, impotence, tremor, confusion and nasal congestion. Many depressive symptoms including anorexia, fatigue, weakness, restlessness and lethargy have been reported as side effects of both Limbitrol and amitriptyline. Granulocytopenia, jaundice and hepatic dysfunction have been observed rarely.

The following list includes adverse reactions not reported with Limbitrol but requiring consideration because they have been reported with one or both components or closely related drugs.

Cardiovascular: Hypotension, hypertension, tachycardia, palpitations, myocardial infarction, arrhythmias, heart block, stroke.

Psychiatric: Euphoria, apprehension, poor concentration, delusions, hallucinations, hypomania and increased or decreased libido.

Neurologic: Incoordination, ataxia, numbness, tingling and paresthesias of the extremities, extrapyramidal symptoms, syncope, changes in EEG patterns.

Anticholinergic: Disturbance of accommodation, paralytic ileus, urinary retention, dilatation of urinary tract.

Allergic: Skin rash, urticaria, photosensitization, edema of face and tongue, pruritus.

Hematologic: Bone marrow depression including agranulocytosis, eosinophilia, purpura, thrombocytopenia.

Gastrointestinal: Nausea, epigastric distress, vomiting, anorexia, stomatitis, peculiar taste, diarrhea, black tongue.

Endocrine: Testicular swelling and gynecomastia in the male, breast enlargement, galactorrhea and minor menstrual irregularities in the female, elevation and lowering of blood sugar levels, and syndrome of inappropriate ADH (antidiuretic hormone) secretion.

Other: Headache, weight gain or loss, increased perspiration, urinary frequency, mydriasis, jaundice, alopecia, parotid swelling.

Overdosage: Immediately hospitalize patient suspected of having taken an overdose. Treatment is symptomatic and supportive. IV administration of 1 to 3 mg physostigmine salicylate has been reported to reverse the symptoms of amitriptyline poisoning. See complete product information for manifestation and treatment.

Dosage: Individualize according to symptom severity and patient response. Reduce to smallest effective dosage when satisfactory response is obtained. Larger portion of daily dose may be taken at bedtime. Single h.s. dose may suffice for some patients. Lower dosages are recommended for the elderly. Limbitrol DS (double strength) Tablets, initial dosage of three or four tablets daily in divided doses, increased up to six tablets or decreased to two tablets daily as required. Limbitrol Tablets, initial dosage at three or four tablets daily in divided doses, for patients who do not tolerate higher doses.

How Supplied: Double strength (DS) Tablets: white, film-coated, each containing 10 mg chlordiazepoxide and 25 mg amitriptyline (as the hydrochloride salt), and Tablets: blue, film-coated, each containing 5 mg chlordiazepoxide and 12.5 mg amitriptyline (as the hydrochloride salt). Available in bottles of 100 and 500, Tel-E-Dose[®] packages of 100, Prescription Paks of 50.



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JULY 1987

See the difference in the first week¹

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In moderate depression and anxiety

Limbitrol[®]

Each tablet contains 5 mg clordiazepoxide and 12.5 mg amitriptyline (as the hydrochloride salt) ^{IV}

Limbitrol[®] DS

Each tablet contains 10 mg clordiazepoxide and 25 mg amitriptyline (as the hydrochloride salt) ^{IV}

ROCHE

Please see summary of product information on adjacent page.

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Aug. 1987

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JOURNAL OF THE MEDICAL ASSOCIATION OF THE STATE OF ALABAMA

DISPLAY
SELVES



Autumn



Winter



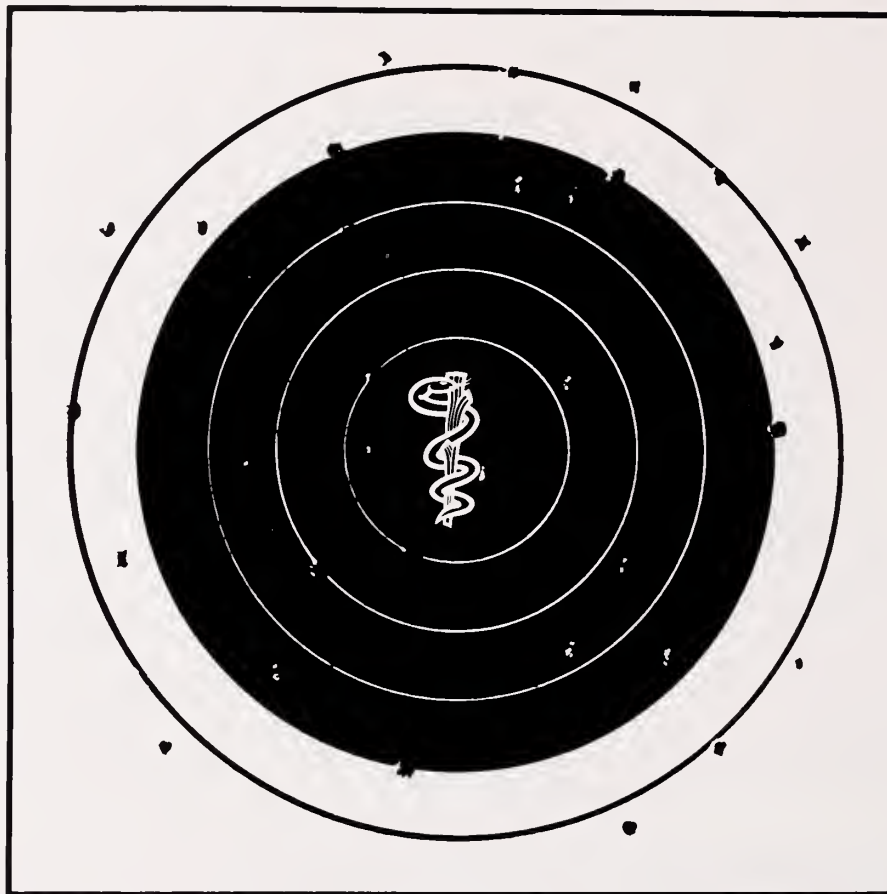
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Summer

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INDERAL[®] LA
(PROPRANOLOL HCl)

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AUG 5 1987

after a major nationwide trial...



An aerial photograph of a large, modern stadium at dusk. The stadium is filled with spectators, and the football pitch is brightly lit. The surrounding area includes a cityscape and a winding road. The text "...we had to find just the right room." is overlaid on the image.

...we had
to find
just the
right room.

60,073 patients (90%) who started on INDERAL[®] LA stayed on INDERAL LA!^{1*}

Surprising? Not really.

Because most patients on INDERAL LA (propranolol HCl) don't even know it's working.

A recent double-blind, placebo-controlled, crossover study in 138 hypertensive patients² revealed that INDERAL LA has a side effects profile unsurpassed by atenolol or metoprolol — which shows how well-tolerated once-daily INDERAL LA can be.

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Fifty-nine percent of the time, INDERAL LA stood on its own.

The patients in the nationwide compliance trial were no different from yours. Generally when the antihypertensive regimen is complicated, compliance may become a problem. So, the effectiveness of INDERAL LA as once-daily monotherapy is a big plus. Of the remaining hypertensives in the program, 36% were treated merely with the addition of a diuretic to INDERAL LA.

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Like conventional INDERAL Tablets, INDERAL LA should not be used in the presence of congestive heart failure, sinus bradycardia, cardiogenic shock, heart block greater than first degree, and bronchial asthma.

*After a 30-day trial with INDERAL LA, physicians reported that 90% of the patients would remain on INDERAL LA.

**The one you know best
keeps looking better**

Please see next page for brief summary of prescribing information

NOW AVAILABLE...
NEW LOW DOSE
INDERAL[®] LA 60 mg
(PROPRANOLOL HCl) LONG ACTING CAPSULES

The one you know best keeps looking better

BRIEF SUMMARY (FOR FULL PRESCRIBING INFORMATION, SEE PACKAGE CIRCULAR)

INDERAL® LA brand of propranolol hydrochloride (Long Acting Capsules)

DESCRIPTION. Inderal LA is formulated to provide a sustained release of propranolol hydrochloride. Inderal LA is available as 60 mg, 80 mg, 120 mg, and 160 mg capsules.

CLINICAL PHARMACOLOGY. Inderal is a non-selective beta-adrenergic receptor blocking agent possessing no other autonomic nervous system activity. It specifically competes with beta-adrenergic receptor-stimulating agents for available receptor sites. When access to beta-receptor sites is blocked by Inderal, the chronotropic, inotropic, and vasodilator responses to beta-adrenergic stimulation are decreased proportionately.

INDERAL LA Capsules (60, 80, 120, and 160 mg) release propranolol HCl at a controlled and predictable rate. Peak blood levels following dosing with Inderal LA occur at about 6 hours and the apparent plasma half-life is about 10 hours. When measured at steady state over a 24-hour period, the area under the propranolol plasma concentration-time curve (AUCs) for the capsules are approximately 60% to 65% of the AUCs for a comparable divided daily dose of Inderal Tablets. The lower AUCs for the capsules are due to greater hepatic metabolism of propranolol, resulting from the slower rate of absorption of propranolol. Over a twenty-four (24) hour period, blood levels are fairly constant for about twelve (12) hours then decline exponentially.

INDERAL LA should not be considered a simple mg-for-mg substitute for conventional propranolol and the blood levels achieved do not match (are lower than) those of two to four times daily dosing with the same dose. When changing to Inderal LA from conventional propranolol, a possible need for titration upwards should be considered especially to maintain effectiveness at the end of the dosing interval. In most clinical settings, however, such as hypertension or angina where there is little correlation between plasma levels and clinical effect, Inderal LA has been therapeutically equivalent to the same mg dose of conventional Inderal as assessed by 24-hour effects on blood pressure and on 24-hour exercise responses of heart rate, systolic pressure and rate pressure product. Inderal LA can provide effective beta blockade for a 24-hour period.

INDICATIONS AND USAGE. Hypertension: Inderal LA is indicated in the management of hypertension. It may be used alone or used in combination with other antihypertensive agents, particularly a thiazide diuretic. Inderal LA is not indicated in the management of hypertensive emergencies.

Angina Pectoris Due to Coronary Atherosclerosis: Inderal LA is indicated for the long-term management of patients with angina pectoris.

Migraine: Inderal LA is indicated for the prophylaxis of common migraine headache. The efficacy of propranolol in the treatment of a migraine attack that has started has not been established and propranolol is not indicated for such use.

Hypertrophic Subaortic Stenosis: Inderal LA is useful in the management of hypertrophic subaortic stenosis, especially for treatment of exertional or other stress-induced angina, palpitations, and syncope. Inderal LA also improves exercise performance. The effectiveness of propranolol hydrochloride in this disease appears to be due to a reduction of the elevated outflow pressure gradient which is exacerbated by beta-receptor stimulation. Clinical improvement may be temporary.

CONTRAINDICATIONS. Inderal is contraindicated in 1) cardiogenic shock, 2) sinus bradycardia and greater than first-degree block, 3) bronchial asthma, 4) congestive heart failure (see WARNINGS) unless the failure is secondary to a tachyarrhythmia treatable with Inderal.

WARNINGS. CARDIAC FAILURE. Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive heart failure, and its inhibition by beta blockade may precipitate more severe failure. Although beta blockers should be avoided in overt congestive heart failure, if necessary, they can be used with close follow-up in patients with a history of failure who are well compensated and are receiving digitalis and diuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitalis on heart muscle.

IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta blockers can, in some cases, lead to cardiac failure. Therefore, at the first sign or symptom of heart failure, the patient should be digitalized and/or treated with diuretics, and the response observed closely. If Inderal should be discontinued (gradually, if possible).

IN PATIENTS WITH ANGINA PECTORIS, there have been reports of exacerbation of angina and, in some cases, myocardial infarction following abrupt discontinuance of Inderal therapy. Therefore, when discontinuance of Inderal is planned, the dosage should be gradually reduced over at least a few weeks, and the patient should be cautioned against interruption or cessation of therapy without the physician's advice. If Inderal therapy is interrupted and exacerbation of angina occurs, it is usually advisable to reinstitute Inderal therapy and take other measures appropriate for the management of unstable angina pectoris. Since coronary artery disease may be unrecognized, it may be prudent to follow the above advice in patients considered at risk of having occult atherosclerotic heart disease who are given propranolol for other indications.

Nonallergic Bronchospasm (eg, chronic bronchitis, emphysema) — PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD IN GENERAL NOT RECEIVE BETA BLOCKERS. Inderal should be administered with caution since it may block bronchodilation produced by endogenous and exogenous catecholamine stimulation of beta receptors.

MAJOR SURGERY. The necessity or desirability of withdrawal of beta-blocking therapy prior to major surgery is controversial. It should be noted, however, that the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.

INDERAL (propranolol HCl), like other beta blockers, is a competitive inhibitor of beta-receptor agonists and its effects can be reversed by administration of such agents, eg, dobutamine or isoproterenol. However, such patients may be subject to protracted severe hypotension. Difficulty in starting and maintaining the heartbeat has also been reported with beta blockers.

DIABETES AND HYPOGLYCEMIA. Beta blockers should be used with caution in diabetic patients if a beta blocking agent is required. Beta blockers may mask tachycardia occurring with hypoglycemia, but other manifestations such as dizziness and sweating may not be significantly affected. Following insulin-induced hypoglycemia, propranolol may cause a delay in the recovery of blood glucose to normal levels.

THYROTOXICOSIS. Beta blockade may mask certain clinical signs of hyperthyroidism. Therefore, abrupt withdrawal of propranolol may be followed by an exacerbation of symptoms of hyperthyroidism including thyroid storm. Propranolol may change thyroid function tests, increasing T_4 and reverse T_3 , and decreasing T_3 .

IN PATIENTS WITH WOLFF-PARKINSON-WHITE SYNDROME, several cases have been reported in which, after propranolol, the tachycardia was replaced by a severe bradycardia requiring a demand pacemaker. In one case, this resulted after an initial dose of 5 mg propranolol.

PRECAUTIONS. GENERAL. Propranolol should be used with caution in patients with impaired hepatic or renal function. Inderal (propranolol HCl) is not indicated for the treatment of hypertensive emergencies.

Beta-adrenergic receptor blockade can cause reduction of intraocular pressure. Patients should

be told that Inderal may interfere with the glaucoma screening test. Withdrawal may lead to a return of increased intraocular pressure.

CLINICAL LABORATORY TESTS. Elevated blood urea levels in patients with severe heart disease, elevated serum transaminase, alkaline phosphatase, lactate dehydrogenase.

DRUG INTERACTIONS. Patients receiving catecholamine-depleting drugs such as reserpine should be closely observed if Inderal is administered. The added catecholamine-blocking action may produce an excessive reduction of resting sympathetic nervous activity which may result in hypotension, marked bradycardia, vertigo, syncope attacks, or orthostatic hypotension.

Caution should be exercised when patients receiving a beta blocker are administered a calcium-channel-blocking drug, especially intravenous verapamil, for both agents may depress myocardial contractility or atrioventricular conduction. On rare occasions, the concomitant intravenous use of a beta blocker and verapamil has resulted in serious adverse reactions, especially in patients with severe cardiomyopathy, congestive heart failure or recent myocardial infarction.

Aluminum hydroxide gel greatly reduces intestinal absorption of propranolol.

Ethanol slows the rate of absorption of propranolol.

Phenyltol, phenobarbital, and rifampin accelerate propranolol clearance.

Chlorpromazine, when used concomitantly with propranolol, results in increased plasma levels of both drugs.

Antipyrene and lidocaine have reduced clearance when used concomitantly with propranolol.

Thyroxine may result in a lower than expected T_3 concentration when used concomitantly with propranolol.

Cimetidine decreases the hepatic metabolism of propranolol, delaying elimination and increasing blood levels.

Theophylline clearance is reduced when used concomitantly with propranolol.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY. Long-term studies in animals have been conducted to evaluate toxic effects and carcinogenic potential. In 18-month studies in both rats and mice, employing doses up to 150 mg/kg/day, there was no evidence of significant drug-induced toxicity. There were no drug-related tumorigenic effects at any of the dosage levels. Reproductive studies in animals did not show any impairment of fertility that was attributable to the drug.

PREGNANCY. Pregnancy Category C. Inderal has been shown to be embryotoxic in animal studies at doses about 10 times greater than the maximum recommended human dose.

There are no adequate and well-controlled studies in pregnant women. Inderal should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

NURSING MOTHERS. Inderal is excreted in human milk. Caution should be exercised when Inderal (propranolol HCl) is administered to a nursing woman.

PEDIATRIC USE. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS. Most adverse effects have been mild and transient and have rarely required the withdrawal of therapy.

Cardiovascular. Bradycardia, congestive heart failure, intensification of AV block, hypotension, paresthesia of hands, thrombocytopenic purpura, arterial insufficiency, usually of the Raynaud type.

Central Nervous System. Light-headedness, mental depression manifested by insomnia, lassitude, weakness, fatigue, reversible mental depression progressing to cataplexy, visual disturbances, hallucinations, vivid dreams, an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics. For immediate formulations, fatigue, lethargy and vivid dreams appear dose related.

Gastrointestinal. Nausea, vomiting, epigastric distress, abdominal cramping, diarrhea, constipation, mesenteric arterial thrombosis, ischemic colitis.

Allergic. Pharyngitis and agranulocytosis, erythematous rash, fever combined with aching and sore throat, laryngospasm and respiratory distress.

Respiratory. Bronchospasm.

Hematologic. Agranulocytosis, nonthrombocytopenic purpura, thrombocytopenic purpura.

Auto-immune. In extremely rare instances, systemic lupus erythematosus has been reported.

Miscellaneous. Alopecia, LE-like reactions, psoriasis-like rashes, dry eyes, male impotence, and Peyronie's disease have been reported rarely. Oculomucocutaneous reactions involving the skin, serous membranes and conjunctivae reported for a beta blocker (practolol) have not been associated with propranolol.

DOSAGE AND ADMINISTRATION. Inderal LA provides propranolol hydrochloride in a sustained-release capsule for administration once daily. If patients are switched from Inderal Tablets to Inderal LA Capsules, care should be taken to assure that the desired therapeutic effect is maintained. Inderal LA should not be considered a simple mg-for-mg substitute for Inderal. Inderal LA has different kinetics and produces lower blood levels. Retitration may be necessary, especially to maintain effectiveness at the end of the 24-hour dosing interval.

HYPERTENSION. Dosage must be individualized. The usual initial dosage is 80 mg Inderal LA once daily, whether used alone or added to a diuretic. The dosage may be increased to 120 mg once daily or higher until adequate blood-pressure control is achieved. The usual maintenance dosage is 120 to 160 mg once daily. In some instances a dosage of 640 mg may be required. The time needed for full hypertensive response to a given dosage is variable and may range from a few days to several weeks.

ANGINA PECTORIS. Dosage must be individualized. Starting with 80 mg Inderal LA once daily, dosage should be gradually increased at three- to seven-day intervals until optimal response is obtained. Although individual patients may respond at any dosage level, the average optimal dosage appears to be 160 mg once daily. In angina pectoris, the value and safety of dosage exceeding 320 mg per day have not been established.

If treatment is to be discontinued, reduce dosage gradually over a period of a few weeks (see WARNINGS).

MIGRAINE. Dosage must be individualized. The initial oral dose is 80 mg Inderal LA once daily. The usual effective dose range is 160-240 mg once daily. The dosage may be increased gradually to achieve optimal migraine prophylaxis. If a satisfactory response is not obtained within four to six weeks after reaching the maximal dose, Inderal LA therapy should be discontinued. It may be advisable to withdraw the drug gradually over a period of several weeks.

HYPERTROPHIC SUBAORTIC STENOSIS. 80-160 mg Inderal LA once daily.

PEDIATRIC DOSAGE. At this time the data on the use of the drug in this age group are too limited to permit adequate directions for use.

*The appearance of these capsules is a registered trademark of Ayerst Laboratories.

REFERENCES:

1. Inderal LA National Compliance Evaluation Program. Data on file, Ayerst Laboratories.
2. Ravid M, Lang R, Jutrin I. The relative antihypertensive potency of propranolol, oxprenolol, atenolol, and metoprolol given once daily. *Arch Intern Med* 1985; 145:1321-1323.

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Helpful to many writers is *The Elements of Style* by William Strunk, Jr., and E. B. White, which emphasizes brevity, vigor and clarity.

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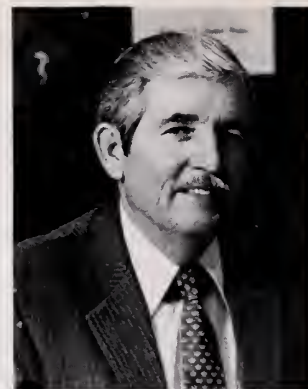
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The Cover

The symbolism of these ancient astrological signs for the seasons should be obvious, deriving from the waxing and waning of life and, in the case of winter, protection in a house from the cold and snow. From Professor Rudolf Koch's classic work, *The Book of Signs*, containing all manner of symbols used, from the earliest times to the Middle Ages, by primitive peoples and early Christians. Dover reprint of the English translation, published by The First Edition Club, London, 1930.

EXECUTIVE DIRECTOR



*S. Lon Conner
Executive Director, MASA*

AIDS in the Age of Anxiety

It has not been too many years since the World Health Organization spoke a virtually unanimous verdict of international public health in declaring smallpox eradicated from the planet.

This was a significant milestone for medical science, since smallpox is believed by many to have had the highest overall total casualty rate of any of the infectious diseases in the history of man.

It was of course an occasion for great rejoicing, for it confirmed what had been the conventional wisdom for years: the great contagions had all been whipped and science could now turn its undivided attention to the "chronic" diseases.

It seemed too good to be true: at long last most of the world was free of most of the major contagious killers. And that's exactly how it turned out — it was too good to be true. Enter AIDS, pronounced by many to be potentially the worst plague in all of human history. Had AIDS come along during some of the earlier plagues, it might have gone unnoticed at first, lost in the general panic.

There may be nothing remotely comparable in the living memory of man. The closest challenge was the great influenza pandemic of 1918-19, which is believed to have caused 20 million deaths worldwide, and more than 500,000 in this country.

That event caused surprisingly little panic. As one scientist has observed, the reasons for that were several: it took place at a time when premature death was all too common; when doctors would do little for *any* infectious disease; the outcome was evident within days or weeks; most victims recovered; and finally, flu epidemics were relatively familiar and would end as others had before.

It is not necessary to put too fine a point on the difference between the flu pandemic of 70 years ago and the AIDS pandemic of 1987. Suffice it to cite only a few of the reasons that AIDS, and the public alarm over it, are so different:

Infectious disease was generally believed, when AIDS appeared in 1981, to be ancient history, and few really believed a new and deadly pandemic of any magnitude was possible. Even with a strange new disease, in this age of miracle medicine it was supposed that some therapeutic agent could be quickly found and, in not much more time, a vaccine as well.

In recent memory, for example, medical science had virtually erased the scourge of polio, at least from the developed nations. No less an authority than Surgeon General Koop, however, believes that a cure for AIDS may *never* be found, considering the complexity of

the disease, and no effective vaccine is likely before the next century.

Another difference is that AIDS appears to be 100% fatal. Treatments such as AZT (Retrovir) merely extend life a few months (or prolong death, as some say).

Still another difference is that few believe AIDS will retreat spontaneously. Before it is done with its havoc, as much as one-quarter of mankind may perish, knowledgeable observers like Stephen Jay Gould are saying.

At first, the general population felt relatively secure. AIDS seemed to be confined to such pariahs as homosexuals, bisexuals and IV drug users. But then the percentage of "innocent victims" began to grow — babies, hemophiliacs, transfusion patients, their sexual partners, and so on.

Back in the days of great syphilis epidemics a label was coined for such innocents. Doctors defined them as victims of *venereal insontium*, venereal disease of the innocent. The AMA has said that transfusion alone, in the period after discovery of AIDS but before adequate testing protection for the nation's blood supply, produced a theoretical total of tens of millions of Americans at risk. That is the number of those who received whole blood or components in this period plus their contacts.

Only in the past few months has the enormity of this peril to human life on earth begun to be widely understood in its ghastly dimensions. It has changed almost everything, from the way you practice medicine, to the public perception of science and technology, already jaundiced by Three Mile Island, the Challenger disaster, Love Canal, the Swine Flu vaccine debacle, Chernobyl, and the rest.

Against this background of disenchantment, can the public really be called benighted when it demands, as anxious parents did in New York and in other cities when physicians told them they had nothing to fear from AIDS children in school: "I don't want all the medical experts telling me, 'Don't worry.' I'm worrying."

Or when intelligent and concerned citizens persisted in their questions: "Can you be certain, Doctor, absolutely certain beyond any doubt, that casual transmissions never occur and cannot occur?"

The answer, given by one medical expert after another, is less than satisfactory to the lay public. That answer, if honestly given, is always a variant of this: "There is, of course, no way to be absolutely certain about almost anything. But there have been absolutely no absolute data to indicate any appreciable risk."

At the risk of appearing to side with the benighted, I can sympathize with those in the general public who are not entirely satisfied by the answers they are getting. While I know no other answer is possible, certainly not at this juncture, those who tend to denigrate public misunderstanding and ignorance should remem-

ber this: to the layman, science had long appeared to be infallible in the brave new world of enlightenment. But science is tarnished in the public eye by a whole host of recent events that cast doubt on that imagined infallibility. I say "imagined" because I know few reputable scientists and virtually no physicians of good report ever claimed infallibility. Far from it. Doctors have insisted down through the recent years of apparent miracles-on-order that medicine remains an inexact science.

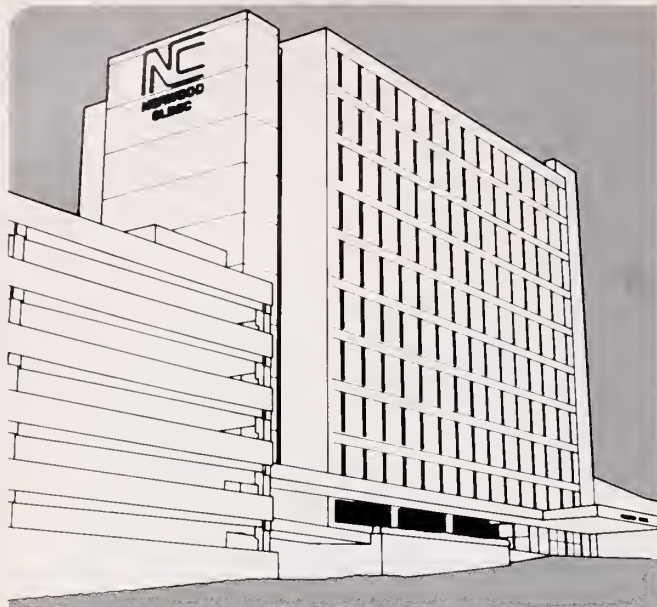
But the expectations of the public deafened it to these repeated protestations of imperfection. Now great numbers of otherwise perceptive people are saying: "I do not believe them. I do not believe they know enough about AIDS to assure me that it cannot be contracted in casual contact. What is casual contact? How about sneezing and coughing? Other viruses can be transmitted in this way, why not AIDS?" And so on.

To repeat, the public's lack of total confidence in public health pronouncements has its root in recent examples of perceived scientific overconfidence. It must always be remembered that the layman is thinking this: If they're wrong, as they have been wrong often before, they will probably admit it and apologize. But that may be too late for my wife, my child and me. We may be dead."

To a dread new disease that is 100% fatal the public wants 100% assurance. Science can't give it. And that is the bottom line of a crisis in public confidence I believe will intensify rather than diminish in the years ahead, as the casualty figures double and then double again.

Add to this public dissatisfaction and distrust the enormous economic burden of this epidemic, as its victims increase exponentially, and you have the ingredients for a very ugly national situation. This will infect all our public affairs in one way or another.





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PRESIDENT'S PAGE



*Carl A. Grote, Jr., M.D.
President, MASA*

Would-Be Junior Doctors

As this is written, the 1987 regular session of the Legislature has a few working days remaining. Because of that, I have no way of knowing the outcome of some bills this month's president's page will address: the attempt by nurse practitioners, therapists and others to gain independent status for their services.

Of course, some of their requests are red herrings, designed to divert attention from the real objective — independent practice; in other words, some kind of limited medical practice through legislative act.

Medical practice in the United States has come a long way since the Flexner Report pretty well brought to an end the absurd permissiveness that allowed just about anybody, qualified or not, to practice medicine. Some of the "doctors" of the time had only brief training in a dubious night school somewhere, or in a bogus "medical school" that was nothing more than a diploma mill.

What the report did was to identify the ways in which the public was being victimized by unqualified practitioners.

About half the medical schools then in existence

vanished soon after the report, which had called them a hoax.

After Flexner, medicine in this country began its long and difficult rise to its present state, with medicine rigidly controlled and certified at every level, from medical school certification through the credentialing process.

Only a few critics along the way have dared charge, as was once routine, that the system is thus under monopoly control of the "medical trust," which has used this control to suppress competition.

While certified medical training is a prerequisite to the practice of medicine, it is arguing in circles to say that doctors thus monopolize the practice.

Of course they do, but only because medical practice in every state require certified training as necessary background before anyone is licensed as competent to assume the position of high trust and responsibility known as medical practice.

Such laws were designed to protect the public from the kind of inadequately trained, or totally ignorant, opportunists who hung out their shingles by the thou-

sands before Flexner. Licensing laws thus provided the enforced standards that made American medicine the best in the world.

But there is an element among paramedical people who believe that they are unfairly denied their chance to practice a little independent medicine by the network of laws that identify them (correctly) as support personnel for physicians. That's galling to a disgruntled few, who feel they have somehow earned the right to free themselves from physician mentors.

They can't come right out and tell the public that they know as much about their branch of medicine as a far more extensively trained physician, so they knock on the back door. When they win one privilege, they will regroup and ask for additional legislation to further extend the fiction that they are, and should be, independent practitioners.

This process of chipping away at regulatory laws is called incrementalism, I believe. You try to do by inches what would surely fail if you attempted it by yards. The ultimate objective of these few paramedical agitators is to practice medicine as junior grade doctors. And some of them won't be satisfied with junior grade for long.

The motivating power of such movements, which have been around as long as medicine has, derives from jealousy, unchecked and irrational ambition, neatly camouflaged by what is displayed as a bid for simple justice.

Unfortunately, they are able to present just enough examples of physicians who have abused their status to make a vaguely plausible case to the poorly informed. That case is designed to elicit from lawmakers and the public this response: "Well, why not?"

Expressed that way, their campaign sounds as American as apple pie. But when a legislature allows its heart to capture its head, it soon finds out, too late, that the real objective of *economic* independence is free-standing *professional* independence.

In other words, legislatures discover, too late, that what the paraprofessionals really wanted was the whole nine yards — with separate billing and other excursions as the diversionary springboard to independent diagnosis and treatment — in short, medical practice.

Having reached the first point by legislative fiat, they go into business for themselves. Not unreasonably, the public assumes such independence must have been sanctioned by law, since medical practice is tightly regulated. Therefore, the public assumes, the new junior doctors have to be qualified to do what their new sign says they do.

Of course, they are no more qualified to practice medicine than they were before separate billing and other dispensations. In short order, all the reforms imposed since Flexner are at risk.

Most of us have known nurses, therapists and others who wanted to become physicians. We encouraged them. Many have gone back into training to *earn* the privilege and responsibility some are now seeking to gain by shortcutting the system.


Nurses, therapists and others who want to practice medicine should, by all means, be encouraged to apply for medical school. While class sizes are still substantial, applications for medical school have fallen off sharply in recent years. That means those in ancillary branches of health care who hanker to be doctors themselves have a better chance than at any time in the last few decades to have a crack at that.

I say: Go for it. It's long and it's tough but if you really want it above all else, it is within reach.

In the next breath, however, I say: Forget the back door approach. You aren't remotely qualified for independent practice. Physicians will oppose you at every turn because public safety is at risk. Additionally, your objectives can only increase overall costs by expanding the delivery system, while creating a second tier of care.

With all the other assaults on medical practice, the public can ill afford a return to the bad old days before 1910 when just about anybody who hankered to play doctor could do so. □

Carl



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Blank space indicates that no such activity has been reported.

Table adapted from Facts and Comparisons (Nov.) 1984 and Catalano RB. The medical approach to management of pain caused by cancer. "Semin Oncol" 1975; 2; 379-92 and Reuler JB, et. al. The chronic pain syndrome: misconceptions and management. "Ann Intern Med" 1980; 93; 588-96.

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Respiratory Depression: At high doses or in sensitive patients, hydrocodone may produce dose-related respiratory depression by acting directly on brain stem respiratory centers. Hydrocodone also affects centers that control respiratory rhythm, and may produce irregular and periodic breathing.

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Acute Abdominal Conditions: The administration of narcotics may obscure the diagnosis or clinical course of patients with acute abdominal conditions.

PRECAUTIONS:

Special Risk Patients: VICODIN should be used with caution in elderly or debilitated patients and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, prostatic hypertrophy or urethral stricture.

Information For Patients: VICODIN, like all narcotics, may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery; patients should be cautioned accordingly.

Cough Reflex: Hydrocodone suppresses the cough reflex; caution should be exercised when VICODIN is used postoperatively and in patients with pulmonary disease.

Drug Interactions: The CNS-depressant effects of VICODIN may be additive with that of other CNS depressants. When combined therapy is contemplated, the dose of one or both agents should be reduced. The use of MAO inhibitors or tricyclic antidepressants with hydrocodone preparations may increase the effect of either the antidepressant or hydrocodone. The concurrent use of anticholinergics with hydrocodone may produce paralytic ileus.

Usage in Pregnancy: Pregnancy Category C. Hydrocodone has been shown to be teratogenic in hamsters when given in doses 700 times the human dose. There are no adequate and well-controlled studies in pregnant women. VICODIN should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nonteratogenic Effects: Babies born to mothers who have been taking opioids regularly prior to delivery will be physically dependent. The intensity of the syndrome does not always correlate with the duration of maternal opioid use or dose.

Labor and Delivery: Administration of VICODIN to the mother shortly before delivery may result in some degree of respiratory depression in the newborn, especially if higher doses are used.

Nursing Mothers: It is not known whether this drug is excreted in human milk; therefore, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS:

Central Nervous System: Sedation, drowsiness, mental clouding, lethargy, impairment of mental and physical performance, anxiety, fear, dysphoria, dizziness, psychic dependence, mood changes.

Gastrointestinal System: Nausea and vomiting may occur; they are more frequent in ambulatory than in recumbent patients. Prolonged administration of VICODIN may produce constipation.

Genitourinary System: Ureteral spasm, spasm of vesical sphincters and urinary retention have been reported.

Respiratory Depression: (See WARNINGS.)

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Revised, April 1982.

5685

1. Hopkinson JH III: *Curr Ther Res* 24: 503-516, 1978
2. Beaver, WT *Arch Intern Med*, 141:293-300, 1981.

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HEALTH OFFICER'S LETTER



C. E. Fox, III, M.D., M.P.H.

Controlling Hypertension

I would like to acquaint you with the services and activities of the Hypertension Branch of the Alabama Department of Public Health. Beyond being the State Health Department's organizational unit to provide statewide hypertension and awareness services, the program offers an expanding three-prong program to control high blood pressure through core service measurement, joint care, and full care treatment.

Alabama's Hypertension program began 12 years ago after a grant was written and funded to establish a single county pilot program in Chambers County. Until recently the medication component existed in only 10 counties; however, we see the public health role expanding.

Of an estimated 840,724 individuals in Alabama with hypertension, 263,470 are indigent, which is defined as less than 150 percent of the federal poverty level. Of these indigent hypertensives, 88.9 percent are uncontrolled, based on a HANES II Survey applied to Alabama.

A core service of the department is to provide blood pressure measurement, confirmation, counseling and referral and follow-up, if necessary. This is available in all counties.

The second service of the department is joint care management. In joint care the patient is responsible for obtaining a private physician and paying for his or her services. All decisions relative to laboratory studies, choice of drugs and diagnostic tests are under the control of the patient's private physician.

Joint care provides an avenue for the health department to work with the private medical community to serve poor patients who are able to obtain care from a private provider. In this interaction, the health department provides three basic functions. The first is to provide drugs, the second to provide blood pressure monitoring and finally patient education. Results of blood pressure checks or information about drug side effects are forwarded to the patient's private physician for decisions. Joint care is offered in Barbour, Butler, Cherokee, Clarke, Clay, Cleburne, Coosa, Covington, Crenshaw, Etowah, Greene, Henry, Lowndes, Marengo, Pickens, Pike, Sumter, Talladega, Tallapoosa and Washington counties.

The third type of service we provide is full care management. Patients eligible for full care service are indigent individuals who are unable to find a private physician or afford medication. In counties where full

care hypertension service are available, the health department contracts with members of the local medical community to see these indigent patients. In some counties the private physicians come to the health department to staff a monthly hypertension clinic, while in others the patients are referred to the private physician's office. Not only are drugs, education and monitoring available for full care patients but also an EKG, baseline blood chemistry and urine, and a hypertension physical, diagnosis and prescription. Currently, full care patients account for 19 percent of all patients served for hypertension through the Alabama Department of Public Health.

Full care is available in Bibb, Calhoun, Chambers, Coffee, Dallas, DeKalb, Geneva, Mobile, Randolph and Tuscaloosa counties.

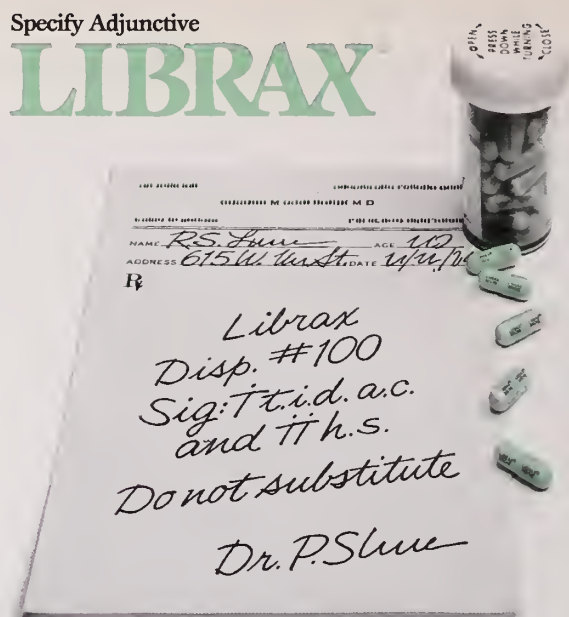
Economic eligibility differs according to the services provided. For those receiving core measurement services there is no income requirement, yet the majority come from the lower end of the economic scale. Joint care patients may have an income level up to 200 percent of the current poverty level. Patients considered full care have more stringent requirements that they be below 150 percent of the poverty level.

Hypertension is a major risk factor for coronary artery disease, cerebrovascular disease and renal failure, thus it is essential that this statewide system of blood pressure control for indigent patients be continued and expanded. ■

Claude Earl Fox, M.D., M.P.H.
State Health Officer

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Usage in Pregnancy: Use of minor tranquilizers during first trimester should almost always be avoided because of increased risk of congenital malformations as suggested in several studies. Consider possibility of pregnancy when instituting therapy.

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As with all anticholinergics, inhibition of lactation may occur. **Precautions:** In elderly and debilitated, limit dosage to smallest effective amount to preclude ataxia, oversedation, confusion (no more than 2 capsules/day initially; increase gradually as needed and tolerated). Though generally not recommended, if combination therapy with other psychotropics seems indicated, carefully consider pharmacology of agents, particularly potentiating drugs such as MAO inhibitors, phenothiazines. Observe usual precautions in presence of impaired renal or hepatic function. Paradoxical reactions reported in psychiatric patients. Employ usual precautions in treating anxiety states with evidence of impending depression; suicidal tendencies may be present and protective measures necessary. Variable effects on blood coagulation reported very rarely in patients receiving the drug and oral anticoagulants; causal relationship not established.

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*Librax has been evaluated as possibly effective as adjunctive therapy in the treatment of peptic ulcer and the irritable bowel syndrome.

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Genesis of Paranoia

Charles H. Smith, M.D.*

Abstract

Some conclusions by the writer expressed in a previous paper on paranoia are summarized.

Parallels and nonparallels between parents of schizoid and paranoid offspring are discussed. Responsibilities, accomplishments and failings of such parents are noted, one hopes in a fair and even handed fashion. The potential value of family support groups such as grandparents, while not discussed in detail, is not underestimated.

The singular position of the Pediatrician to act in both a preventive and therapeutic capacity is discussed at some length. The frequently predestined failure of the teacher as advisor and return of the parents to Pediatrician is recognized.

Two possible avenues of cooperation between Pediatrician and Psychiatrist are explored.

The value of antidepressant and antipsychotic medications in altering the course of paranoia is felt worthy of mention.

Introduction

In an earlier paper (*Views on Paranoia*), the writer stated that consistent denigration by the parents or caretakers is essential to conversion of the child into a paranoid adolescent or adult. During further examination of Paranoids, nothing has been unearthed to change that view. Rather, that view has been reinforced by the taking of more exhaustive childhood histories.

Also in the earlier writing, some considerable emphasis was placed upon the fact that Paranoia and Schizophrenia are separate disease entities which often coincide at a given time in a given patient. But definitely they are separate. In terms of nosology, Paranoid Schizophrenia probably should be abolished. Schizophrenic Disorder (of whatever subtype) with concurrent Paranoia would be more to the point. But the label of Paranoid Schizophrenia has become ingrained and will remain a part of medical literature. It should not, however, become a part of our thinking in dealing with the dynamics of two differing illnesses.

Causal Factors

We can accurately say that the proponents of the "scapegoat" theory of Schizophrenia embrace the notion of parental denigration. It is true that there is much

*Psychiatry, 1909 Walnut St., Montgomery, AL 36106.

to be said for the scapegoat perception which holds that the most vulnerable child in the family is sacrificed to preserve the sanity or emotional well-being of the family as a whole. The result is felt to be the "nurturing" needed to produce an adult Schizophrenic.

The Paranoidogenic parents may well cry "foul." What sort of sport is involved in knocking over an already sitting duck? The vulnerable child can be effectively disposed of in a matter of months or a year.

The parents in the process of Paranoid production want a sturdier victim. They will likely devote their best efforts to the cocky, seemingly self-sufficient offspring. A pursuit of this sort may well require one or two decades depends on the victim's resources.

Might we assume that the parents of the future Paranoid are of hardier psychological stock than those of the developing Schizophrenic? Family histories of both seem to suggest that this assumption is valid.

The above might be illustrated by brief case presentations: 1) A thirty-three-year old Viet Nam veteran presents with strong paranoid trends but seemingly only one delusion, that he had spoken with God while overseas and has been instructed to take whatever steps necessary to save the world. He has not used drugs. His mother is a respected black municipal employee. His father may drink excessively but reports to work on a daily basis. A brother is an Army Master Sergeant. The veteran, 6'5" and 250 pounds, is entirely non-violent. Following an unsuccessful marriage, he decides that, for the time being, any plans for future marriage should be discarded. After a few months in therapy, he (apparently) becomes free of Messianic delusions and is currently concentrating on his own well being.

2) A second Viet Nam veteran presents with flat affect, blocking of speech, splitting of associations, primary process thinking, hallucinations, and multiple delusions, mostly paranoid and primarily aimed at the Veterans Administration, obviously a convenient target for the psychotic veteran. After multiple VA hospitalizations, he remains delusional and has stopped his antipsychotic medications. It is only a matter of time until he will be hospitalized again. The writer had for several years treated his sister for depression, felt to be on a schizo affective basis. Both parents have a history of psychiatric hospitalization.

As brief as promised, it is hoped that some point has been made. Veteran 1) was the object of verbal abuse by his father. To what extent the mother may have condoned or potentiated the patient's abuse during childhood is not really known. She is, if anything, too protective of the patient at present but he is in the process of slowly but firmly cutting the cord. His prognosis appears good.

Veteran 2) is the product of an unstable family and his prognosis is poor. One always hopes for a miracle but there is no reason to expect one.

The Parents as Villains

We might easily conclude, on the basis of what has been written, that the parents of Schizoid children and Paranoid young persons are necessarily evil. This is not usually the case. We are a civilized people and in the majority do what we think is best for our children. We love them and are not at all reluctant to say so. We make mistakes but we make honest mistakes. Emphasis may have simply shifted from physical to psychological error. The mother who avoids bothering her pediatrician at 3:00 AM when her month old child spikes a temperature of 106° has probably made a lethal error. For the psychologically mismanaged child, there is generally at least a second try.

It is very true that there are children who are knowingly abused by a parent or parents. Such abuse may be physical, psychological or both. And it is true that there are numerous incidents in which the parent does abuse and does so in the absence of major mental or emotional disorder. Such parents are criminals and should be treated accordingly. The mother who allows father/daughter incest knowingly and without "blowing the whistle" is, in the writer's view, even more guilty than the father. The father can at least plead glandular drive. The mother may prate of "keeping the family together" but in such an instance specious rationalization has no place.

We do have the obligation to investigate any possibility of serious parental emotional disturbance in any instance of abuse. We have an ethical responsibility to pursue this to an end point. We know the proper routes to take and we know that cooperation with appropriate legal authority may be necessary. While the incestuous parent may be a criminal, there is no body of knowledge to convince us that he is "cured" by a prison term.

Similarities in Parents of Schizophrenics and Paranoids

We all, whatever our own shortcomings, or those of our children, have a need for self esteem. Such a need is paramount to our existence and lacking self esteem we may feel compelled to commit suicide. We can perpetuate our sense of worth through our children, grandchildren or foster children. We speak proudly of their accomplishments publicly but may privately take them to task if we feel they have failed us. This is an entirely selfish view but it may well be a universal attitude and a timeless one. Ancient Egyptian marital practices would not now be legally permitted but they served the purpose of providing a sense of self worth through self perpetuation. Pyramids did the same.

So it is probably accurate to state that both parents of Schizophrenic children and parents of Paranoid children perform as they do, usually (not always) unconsciously in an effort to maintain self esteem. The for-

mer do so in hope of eliminating a weak link in the family chain, the latter out of fear, a fear that the child might ultimately prove more competent than the parents and siblings and destroy their collective self esteem.

Other Factors in Paranoia

These seem fairly obvious but the obvious is often worth repeating. Very passive parents may surrender a dominant role to a grandparent or uncle or even to their older child. Such passivity would seem to bode ill and probably usually does. But a poor outcome is not predestined. The parents, for whatever reason or reasons, may be psychologically impotent and a positive and self assured grandfather might be just what the doctor ordered. This will not often be the case for an indefinite period. The parents will hopefully recover and regroup and resume responsibility, an act which might hurt grandfather's feelings. For reasons which probably still have to do with the extended family, black parents welcome both the intervention and ongoing assistance of a grandparent. Often grandparents are expected to permanently contribute to the well being of their "grands."

A father or mother may for physical or emotional reasons be an absentee. Whichever parent is absent, an additional burden clearly accrues to the other. This is a handicap but not at all an insoluble one. The remaining parent may have the strength to take over and there are generally relatives and friends. Even physicians might be of help. More of physicians later.

The Parental Predicament

Parents read books, newspaper advice columns, watch television productions and may hold group meetings, often with a minister, priest or rabbi as moderator. They do this in hope of better understanding themselves and their children. They do this in striving to determine the role of Divine intervention or Divine empathy.

If the parent is overly demanding or critical he/she may be at risk of producing a psychotic child. If too permissive, there is danger of producing a Personality Disorder, a social misfit. Such a situation may result in a *dilemma*, by definition, a choice between two mutually unsatisfactory courses of action. Here the help of the minister can be invaluable. The wise and understanding pastoral counselor can help the parents choose a middle ground even when none seems to exist. At worse, he can reassure erring parents that their errors are not those of deliberate commission if such is the case. The key words are *wise* and *understanding*. Ministers are human and lacking some expertise should not counsel. Neither should priests be randomly assigned to receive confession. The mission of the minister/priest/rabbi is to help resolve the di-

lemma, not compound it. An overly simplified solution may produce a dismally diffident resolution.

The Role of the Physician

Most parental misgivings will be heard by the internist or family physician. They will be heard while the parent is in for a check on response to an antihypertensive drug or resolution of a urinary tract infection. "By the way, doctor, our fourteen year old son, Jimmy, is refusing to go to school, should we make him go or do you think he is just going through a phase (phase of what)?" What in the world is the poor physician to say? He can't possibly say "The kid has obvious emotional problems, take him to a psychiatrist or psychologist and get him expert help." This will offend the patient and it may be inaccurate advice. The parents or the homeroom teacher may be the persons in need of straightening out. A not unusual "compromise" will be to suggest bringing in the youngster in three months for a thorough physical examination. By then, school will be out and that particular problem will be over until Jimmy is fifteen and again refuses to attend class. Thus it goes until this Jimmy or another Jimmy burglarizes a store, punches a teacher or shoots a parent. Are things really so bad? No, but they are not good and they don't seem to be getting better. This is not a time for pathological optimism. Parents have taken to waiting much too long for things to "work themselves out."

Prevention of Paranoia: The Pediatrician

As a pediatrician turned psychiatrist, the writer insists upon his right to remain in the pediatric fraternity. As a group (we) pediatricians are something of a prickly bunch. We feel that we are overworked and underpaid and we are entirely correct. We feel we are often scorned by other professionals until they are presented with a moribund child and we are again totally right. We know that our familiarity with fluid and electrolyte balance is superior to that of a skilled surgeon and the surgeon in need will not argue. We can do an intravenous cutdown and initiate I.V. fluids while the surgeon is still debating a point of incision. These things we do through practice. By the end of residency, they require small mentation and no deliberation. Residency is a fun time, a time during which we are privileged to see and treat a broad spectrum of exotic illness referred from many geographic areas.

Practice is dull time when we treat sore throats, earaches, do routine physicals and only occasionally see an unusual, thought provoking illness. Practice is also the time during which we have the very rare, almost unique opportunity to observe parent/child interaction in the raw. The family may become secretive toward the psychiatrist. They assume the pediatrician to entirely concentrate on the infant's herniated belly

button. While one does not wish to demean the belly button one can hope that other things are also demanding the pediatrician's attention.

There are so many things to be noted, so many questions to be asked and, as always, so little time. The pediatrician, in order to make a decent livelihood, rushes from patient to patient, examining room to examining room. But it is upon this overworked physician that we must rely to report, or at least note, initial symptoms of child and parent pathology.

Why does Dr. K., an assistant professor of English at a nearby state university, invariably always bring his nearly always ill five children to the office alone? Why is Mrs. K. never present? After one year, one asks. The answer is simple and seems to relieve Dr. K. Mrs. K. has been diagnosed as a Paranoid Schizophrenic. She spends a good part of any year in the hospital. When at home, she refuses medication and physically abuses the children.

Mrs. C., mother of two, always brings her children, quite healthy, for examination every month. During a routine and negative examination, one asks about the well being of Mr. C. and is told that he is bisexual and one is told in no uncertain terms by this very attractive lady about the phenomenon of transference. The pediatrician is confused. He has not been taught of transference. He might suspect it in teenage patients. But in a parent, no.

The point of the above mentioned case reports is simple. To get answers one asks questions. Nothing could be more obvious. And nothing more neglected. Perhaps there are times when we would rather not hear any answers.

The pediatrician is forced to become an acute observer. Forced because his young patient is usually unable to give a comprehensive history. History given by the parents is often conflicting. While inserting a probing digit or instrument into a given orifice, there is ample opportunity to watch for hostile glances between parents or from parents to child. While visualizing an eardrum through otoscope, there is time to say "This child seems physically okay but there is something in the family which doesn't seem quite right. I may be wrong. Why don't we go to my office and discuss it?"

The pediatrician and only the pediatrician can make this sort of suggestion, command, really, and can make it stick and can do so without alienating the parents. An hour in the office isn't necessary. If something is in fact wrong, the parents are aware of it and are eager to discuss it with a physician whom they respect. Parents may be chary of discussing family problems with their internist, fearful of a psychiatrist or psychologist but quite prepared to speak where the child is the focus of attention. The pediatrician can and should make suggestions and can do so with near certainty that they will be carried out. He will then arrange follow up

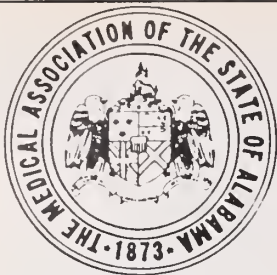
consultation within a given period of time, e.g., "Let's get together in a month to take a look at things." The pediatrician should, as we all should, qualify the limits of his expertise. In the present era of lawsuits *uber alles*, he and we are going to do so.

It is within the power and competence of the pediatrician to nip paranoia and many other emotional illnesses in the bud. But the spectre of the courtroom lingers. It both lingers and flourishes. "Now, doctor, would you explain to the court during what part of your pediatric training you became an expert in giving parents advice as to proper psychological counsel in child rearing?" How does one explain to the satisfaction of judge and jury that, however much one may have memorized, the clinical practice of medicine (any field) is primarily an art, not a science? "Are you saying, doctor, that after so many years of schooling, you acted out of intuition, not your many years of training?" How to explain in court? It is suspected that in private conversation the successful attorney would say that while he wants the best training available or affordable, he could not be successful without a "feel" for the law. And what is a "feel" for the law? It is an intuitive grasp of psychology.

Pediatricians, like other physicians, are fed up with comments on law. Hopefully they remain a group who value their autonomy. And hopefully they will continue to advise where advice is needed and the devil take the vultures.

Parents, as mentioned, are prone to view their child's errant behavior as just a "phase" and certainly they may be right. It is of equal possibility they may be woefully wrong. As parents, we want to look at our children as normal. We may dismiss slipping or plunging grades in our fourteen year old as simply reflecting an onset of interest in the opposite sex to the detriment of concern with academics. A mild decline in grades might reflect the child's growing respect for his/her hormones and some bewilderment as to how to deal with glandular maturation. It can be no secret that most adolescents compromise through masturbation. When an A or B or C student becomes a failing one, "phase" is just not a satisfactory or complete explanation. Parents will usually consult their child's teachers when grades plummet. The teacher labors under a distinct disadvantage. Most usually, he or she will not really know the parents. The parents may present figuratively hat in hand, ready with "Yes, sirs" and "No, ma'ams." What can the teacher say to these strange, little known or unknown persons? Should the teacher suspect serious psychopathology he/she is in no position to suggest psychiatric or psychological consultation. In the event of such a suggestion, parental platitudes may quickly convert into threats, threats toward teacher, principal, Board of Education, etc. "We came for constructive suggestions, not insults to our intel-

continued on page 36



CALL FOR PAPERS

Medical Association of the State of Alabama FOURTH INVITATIONAL SCIENTIFIC SYMPOSIUM

Saturday, January 23, 1988 — 9 a.m. to 4 p.m.
The Wynfrey Hotel, Riverchase Galleria, Birmingham

Purpose of the Program — This program is designed to allow Alabama physicians to share with their colleagues current research efforts and professional concerns. Topics selected will cover a wide range of medical interests.

Program Format — The program will be structured from the papers submitted by Alabama physicians. Depending on the number of papers received, topics, etc., some papers will be presented orally while others may be part of a manuscript discussion period led by a moderator. Registrants and participants will receive advance copy of all papers.

Paper Selection — Papers will be selected using the following criteria and procedures.

1. The subject matter should be of interest to physicians in a number of specialties. Emphasis should be on medical problems which may be encountered by primary care physicians.
2. This is a program designed for and presented by Alabama physicians, so current local research efforts and professional concerns will be given top consideration.
3. The paper should be one that can be adequately outlined and covered in 20 minutes with additional time for questions. Selectees will be expected to prepare suitable written material to be used with the presentation for the study and use of the attendees.
4. On the final review of papers, members of the MASA Council on Medical Education will select topics from a variety of specialties and physician interests to offer a balanced program of general interest.

Symposium Timetable . . . August 15 to October 15, 1987 — Call for abstracts. October 15, 1987 — Final date for abstracts to be received. Late October, 1987 — Review of abstracts by the Council on Medical Education and final selection of papers. November-January 1988 — Announcement of selections; publicity and promotion of Symposium, printing of abstracts and handouts. January 23, 1988 — Program in Birmingham.

Symposium Topics — To acquaint potential presentors with the kinds of subjects that might be suitable, the speakers and topics at the 1986 Symposium are listed below.

Robert L. Baldwin, M.D. — **Current Concepts Regarding Hearing Loss and Its Therapy**; S. Hutson Hay, M.D. — **Photography in the Detection of Eye Disease in Children**; William M. Sanders, M.D. — **Psychiatric Referral of the Difficult Patient**; David L. Rader, M.D. — **Lasers in Medicine and Surgery**; Charles W. Pruet, M.D. — **Common Departures from Sound Management in Head and Neck Cancer**; R. Jay Smith, M.D. — **The Spectrum of Surgical Therapy for Primary Carcinoma of the Breast**; Carl J. Sanfelippo, M.D. — **Prostate Cancer — Current Concepts and Managements**; Gary D. Monheit, M.D. — **The Moh's Technique: Micrographic Surgery for Problem Skin Cancer**; Richard D. Meyer, M.D. — **Obstetrical Palsy, Current State of the Art**; Roger W. Boswell, M.D. — **Acute Care and Chronic Medical Illness**; Larry W. Epperson, M.D. — **Treatment of Vascular Headaches**; Thomas Gaskin, M.D. and Bruce Tucker, M.D. and Linda Zwirlein, R.N., M.S. — **Home Parenteral Therapy**; John L. Mathews, M.D. — **Retrospective Review of Permanent Pacemakers**; Rudolph Navari, M.D., Ph.D. — **Use of Biological Response Modifiers in Treatment of Cancer**.

Abstracts — Abstracts of the proposed paper (200-300 words, double-spaced) should be sent to the Council on Medical Education, using the form below, or a similar format.

ABSTRACT

TO: Council on Medical Education, MASA, P.O. Box 1900-C, Montgomery, AL 36197

I would like to present a paper at the MASA Invitational Symposium on Saturday, January 23, 1988 at the Wynfrey Hotel in Birmingham. An abstract (200-300 words double-spaced) is attached.

I would like to be considered for:

- ☐ Oral presentation of complete paper only
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References: 1. Feighner JP, et al. *Psychopharmacology* 61:217-225, Mar 22, 1979. 2. Data on file, Hoffmann-La Roche Inc., Nutley, NJ. 3. Dixon R, Cohen J. *J Clin Psychopharmacol* 3:107-109, Apr 1983.

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Warnings: Use with great care in patients with history of urinary retention or angle-closure glaucoma. Severe constipation may occur in patients taking tricyclic antidepressants and anticholinergic-type drugs. Closely supervise cardiovascular patients. (Arrhythmias, sinus tachycardia and prolongation of conduction time reported with use of tricyclic antidepressants, especially high doses. Myocardial infarction and stroke reported with use of this class of drugs.) Caution patients about possible combined effects with alcohol and other CNS depressants and against hazardous occupations requiring complete mental alertness (e.g., operating machinery, driving).

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Neurologic: Incoordination, ataxia, numbness, tingling and paresthesias of the extremities, extrapyramidal symptoms, syncope, changes in EEG patterns.

Anticholinergic: Disturbance of accommodation, paralytic ileus, urinary retention, dilatation of urinary tract.

Allergic: Skin rash, urticaria, photosensitization, edema of face and tongue, pruritus.

Hematologic: Bone marrow depression including agranulocytosis, eosinophilia, purpura, thrombocytopenia.

Gastrointestinal: Nausea, epigastric distress, vomiting, anorexia, stomatitis, peculiar taste, diarrhea, black tongue.

Endocrine: Testicular swelling and gynecomastia in the male, breast enlargement, galactorrhea and minor menstrual irregularities in the female, elevation and lowering of blood sugar levels, and syndrome of inappropriate ADH (antidiuretic hormone) secretion.

Other: Headache, weight gain or loss, increased perspiration, urinary frequency, mydriasis, jaundice, alopecia, parotid swelling.

Overdosage: Immediately hospitalize patient suspected of having taken an overdose. Treatment is symptomatic and supportive. IV administration of 1 to 3 mg physostigmine salicylate has been reported to reverse the symptoms of amitriptyline poisoning. See complete product information for manifestations and treatment.

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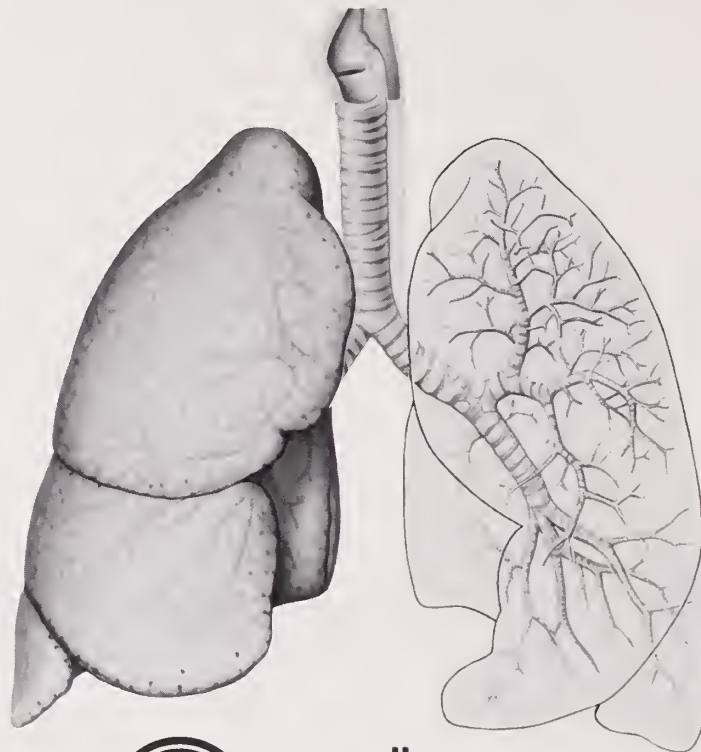


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Indications: Lower respiratory infections, including pneumonia, caused by susceptible strains of *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Streptococcus pyogenes* (group A β -hemolytic streptococci).

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Warnings:

CECLOR SHOULD BE ADMINISTERED CAUTIOUSLY TO PENICILLIN-SENSITIVE PATIENTS. PENICILLINS AND CEPHALOSPORINS SHOW PARTIAL CROSS-ALLERGENICITY. POSSIBLE REACTIONS INCLUDE ANAPHYLAXIS.

Administer cautiously to allergic patients. Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics. It must be considered in differential diagnosis of antibiotic-associated diarrhea. Colon flora is altered by broad-spectrum antibiotic treatment, possibly resulting in antibiotic-associated colitis.

Precautions:

- Discontinue Ceclor in the event of allergic reactions to it.
- Prolonged use may result in overgrowth of nonsusceptible organisms.
- Positive direct Coombs' tests have been reported during treatment with cephalosporins.
- Ceclor should be administered with caution in the presence of markedly impaired renal function. Although dosage adjustments in moderate to severe renal impairment are usually not required, careful clinical observation and laboratory studies should be made.
- Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.
- Safety and effectiveness have not been determined in pregnancy, lactation, and infants less than one month old. Ceclor penetrates mother's milk. Exercise caution in prescribing for these patients.

Adverse Reactions: (percentage of patients)

Therapy-related adverse reactions are uncommon. Those reported include:

- Gastrointestinal (mostly diarrhea): 2.5%.
- Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment.
- Hypersensitivity reactions (including morbilliform eruptions, pruritus, urticaria, and serum-sickness-like reactions that have included erythema multiforme [rarely, Stevens-Johnson syndrome] or the above skin manifestations accompanied by arthritis/arthralgia and, frequently, fever): 1.5%; usually subside within a few days after cessation of therapy. Serum-sickness-like reactions have been reported more frequently in children than in adults and have usually occurred during or following a second course of therapy with Ceclor. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome.
- Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy.
- As with some penicillins and some other cephalosporins, transient hepatitis and cholestatic jaundice have been reported rarely.
- Rarely, reversible hyperactivity, nervousness,

insomnia, confusion, hypertonia, dizziness, and somnolence have been reported.

- Other: eosinophilia, 2%; genital pruritus or vaginitis, less than 1%; and, rarely, thrombocytopenia.

Abnormalities in laboratory results of uncertain etiology

- Slight elevations in hepatic enzymes.
- Transient fluctuations in leukocyte count (especially in infants and children).
- Abnormal urinalysis; elevations in BUN or serum creatinine.
- Positive direct Coombs' test.
- False-positive tests for urinary glucose with Benedict's or Fehling's solution and Clintest[®] tablets but not with Tes-Tape[®] (glucose enzymatic test strip, Lilly).

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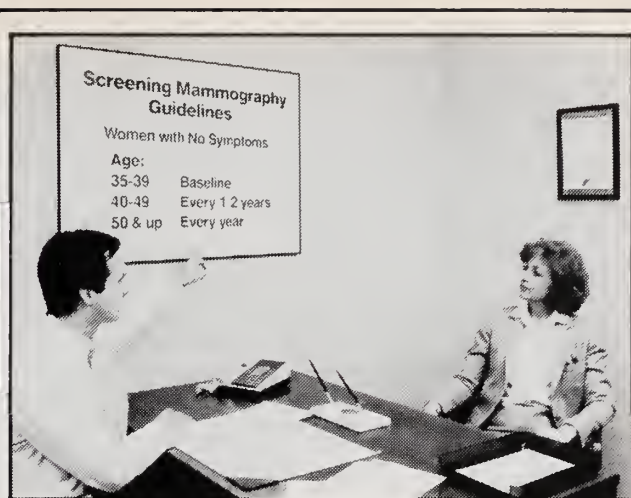
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Genesis of Paranoia

continued from page 21

ligence and that of our children." And so on.

Whoever invented "phase" in the presently used context should be grouped with whoever first stated "they say" and be drawn and quartered. But these people will never be discovered.

The parent-teacher consultation having failed, where do the parents go? To the one person who knows them and their child. The person who may have examined their febrile child with father in his T shirt and mother in gown and robe. That person who knows the parents not dressed in churchly garb. That person not reluctant to speak plainly, clearly and critically. That person is, of a certainty, the pediatrician.

The Role of the Pediatrician and Psychiatrist

A psychiatrist will soon learn not to give the pediatrician unsolicited advice. A psychiatrist who has functioned as a pediatrician knows quite well to avoid gratuitous commentary. The confidence, which some colleagues in other fields deem arrogance, does not seem to be declining among those who practice child and adolescent care. There is no physician in another specialty who is in a position to hone in so quickly on the parental negativism which seems imperative to the creation of the Paranoid. Father in T shirt and mother in gown and robe may feel only a physical obligation to the febrile child. Indeed, during the examination they may berate the child for getting doctor out of bed after office hours. How often they delay contacting the doctor that the child is ill during regular hours we will not know. We can say that the child is rendered much more "beratable" at 2:00 AM than at 2:00 PM. This worthless individual has not only interrupted the rest of the physician, but of parents, brothers and sisters.

Let us suppose that the pediatrician has had one or more consultations with the parents, that he has advised them to "let up" on their criticism, to compliment behavior which is good and minimize flagellation for that which is perceived as onerous and feels that little has been accomplished. The doctor may then decide upon psychiatric referral.

Psychiatric referral may take at least two possible routes. The child and parents may be seen by the psychiatrist in several consultative sessions and then psychiatrist and referring physician can compare notes and decide on future approach. Psychiatrist and referring physician may conclude that referring physician continue primary care with periodic consultative interventions by the psychiatrist. This may often be the best decision. However, it may be concluded that things have gone too far, that the child or adolescent needs to enter active therapy.

Child therapy is expensive because it is necessarily intensive. During the initial weeks, at least, anything

less than weekly sessions is not worthwhile. In dealing with the youngster headed for paranoia, therapists and parents will, in the beginning, be working at cross purposes. The therapist has an hour weekly during which to enforce the patient's sense of self worth and independence of the criticism of others. The parents have all of the remaining hours of the week to undo what might have been accomplished. If all such parents were deliberately, maliciously and entirely consciously bent upon destruction of their child, then that child would be doomed. But this thankfully is not the usual situation. As was earlier noted, the parents may be reacting to a show of strength on the part of the patient and in doing so unwittingly lapse into a destructive set of attitudes. It becomes clear that the therapeutic effort must involve the parents as well as the child. It is not difficult for the therapist to fall into a countertherapeutic countertransference in which "you and I" (child and therapist) operate against "them" (the parents). This is a fatal attitude. Fatal to child, parents and ultimately the therapist.

Use of Medications in Older Children and Adolescents

With the exception of hyperactive children and those with nocturnal enuresis, and a few others such as adolescent Narcoleptics, we have generally scorned the use of medication.


Fairly recently we learn from child psychiatrists and psychologists that the older child or adolescent who is depressed is as deserving of antidepressant pharmacotherapy as the adult. There is no law which says the eighteen year old will respond to antidepressants but the fourteen year old will not, other than the unwritten one formulated by behavioral psychologists. Can anyone be much more depressed than the child destined for paranoia who daily endures the slings and arrows of outraged and outrageous parents? We think not.

Because of the possible side effects of antipsychotic drugs, one entertains the prospect of prescribing the Neuroleptics with a great deal of caution. About the wisest thing one can say is that the therapist who foresees only a grave outcome without medical intervention must do what he thinks best. It isn't easy to imagine a side effect quite so grave as a paranoid psychosis.

Summary and Conclusion

Any discussion of the pathogenesis of paranoia must remain modest in scope and goal. Modesty is dictated by our present relative state of ignorance and there is no question that we are confined in our knowledge.

The object of this paper is not to underscore that which we do not yet know. Rather it has been to explore and define what we do know and to discuss the ways in which our knowledge can best be used in treatment of our patients. We can say, within the bounds of modesty, that we know more than we realize. □



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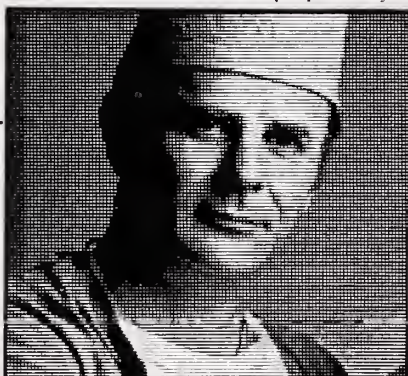
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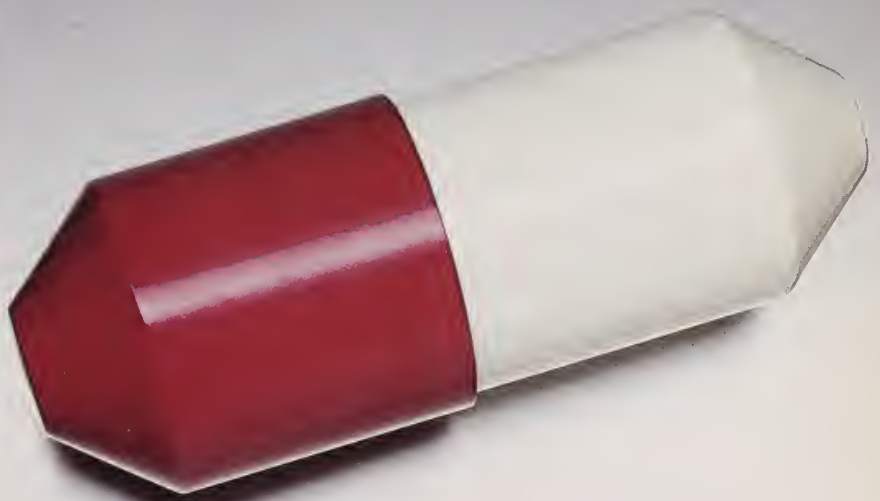
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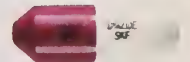


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See next page for references and Brief Summary of Product Information.

ZAN375 July 1987

References: 1. Silvis SE, Griffin J, Hardin R, et al: Final report on the United States multicenter trial comparing ranitidine to cimetidine as maintenance therapy following healing of duodenal ulcer. *J Clin Gastroenterol* 1985;7(6):482-487.
2. Gough KR, Karman MG, Bardhan KD, et al: Ranitidine and cimetidine in prevention of duodenal ulcer relapse: A double-blind, randomised, multicentre, comparative trial. *Lancet* 1984;ii:659-662.

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2. **Maintenance therapy** for duodenal ulcer patients at reduced dosage after healing of acute ulcers.
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CONTRAINDICATIONS: ZANTAC® is contraindicated for patients known to have hypersensitivity to the drug.

PRECAUTIONS: Symptomatic response to ZANTAC® therapy does not preclude the presence of gastric malignancy.

Since ZANTAC is excreted primarily by the kidney, dosage should be adjusted in patients with impaired renal function (see **DOSAGE AND ADMINISTRATION**). Caution should be observed in patients with hepatic dysfunction since ZANTAC is metabolized in the liver.

False-positive tests for urine protein with Multistix® may occur during ZANTAC therapy, and therefore testing with sulfasalicylic acid is recommended.

Although recommended doses of ZANTAC do not inhibit the action of cytochrome P-450 enzymes in the liver, there have been isolated reports of drug interactions which suggest that ZANTAC may affect the bioavailability of certain drugs by some mechanism as yet unidentified (eg, a pH-dependent effect on absorption or a change in volume of distribution).

Lack of experience to date precludes recommending ZANTAC for use in children or pregnant patients. Since ZANTAC is secreted in human milk, caution should be exercised when administered to a nursing mother.

ADVERSE REACTIONS: Headache, sometimes severe, seems to be related to ZANTAC® administration. Constipation, diarrhea, nausea/vomiting, and abdominal discomfort/pain have been reported. There have been rare reports of malaise, dizziness, somnolence, insomnia, vertigo, tachycardia, bradycardia, premature ventricular beats, and arthralgias. Rare cases of reversible mental confusion, agitation, depression, and hallucinations have been reported, predominantly in severely ill elderly patients.

In normal volunteers, SGPT values were increased to at least twice the pretreatment levels in 6 of 12 subjects receiving 100 mg qid IV for seven days, and in 4 of 24 subjects receiving 50 mg qid for five days. With oral administration there have been occasional reports of reversible hepatitis, hepatocellular or hepatocanalicular or mixed, with or without jaundice.

There have been rare reports of reversible leukopenia, granulocytopenia, thrombocytopenia, and pancytopenia.

Although controlled studies have shown no antiandrogenic activity, occasional cases of gynecostasia, impotence, and loss of libido have been reported in male patients receiving ZANTAC, but the incidence did not differ from that in the general population.

Incidents of rash, including rare cases suggestive of mild erythema multiforme, and, rarely, alopecia, have been reported, as well as rare cases of hypersensitivity reactions (eg, bronchospasm, fever, rash, eosinophilia) and small increases in serum creatinine.

OVERDOSAGE: Information concerning possible overdosage and its treatment appears in the full prescribing information.

DOSAGE AND ADMINISTRATION: Active Duodenal Ulcer: The current recommended adult oral dosage is 150 mg twice daily. An alternate dosage of 300 mg once daily at bedtime can be used for patients in whom dosing convenience is important. The advantages of one treatment regimen compared to the other in a particular patient population have yet to be demonstrated.

Maintenance Therapy: The current recommended adult oral dosage is 150 mg at bedtime.

Pathological Hypersecretory Conditions (such as Zollinger-Ellison Syndrome): The current recommended adult oral dosage is 150 mg twice a day. In some patients it may be necessary to administer ZANTAC 150-mg doses more frequently. Doses should be adjusted to individual patient needs, and should continue as long as clinically indicated. Doses up to 6 g/day have been employed in patients with severe disease.

Benign Gastric Ulcer: The current recommended adult oral dosage is 150 mg twice a day.

GERD: The current recommended adult oral dosage is 150 mg twice a day.

Dosage Adjustment for Patients with Impaired Renal Function: On the basis of experience with a group of subjects with severely impaired renal function treated with ZANTAC, the recommended dosage in patients with a creatinine clearance less than 50 ml/min is 150 mg every 24 hours. Should the patient's condition require, the frequency of dosing may be increased to every 12 hours or even further with caution. Hemodialysis reduces the level of circulating ranitidine. Ideally, the dosage schedule should be adjusted so that the timing of a scheduled dose coincides with the end of hemodialysis.

HOW SUPPLIED: ZANTAC® 300 Tablets (ranitidine hydrochloride equivalent to 300 mg of ranitidine) are yellow, capsule-shaped tablets embossed with "ZANTAC 300" on one side and "Glaxo" on the other. They are available in bottles of 30 (NDC 0173-0393-40) and unit dose packs of 100 tablets (NDC 0173-0393-47).

ZANTAC® 150 Tablets (ranitidine hydrochloride equivalent to 150 mg of ranitidine) are white tablets embossed with "ZANTAC 150" on one side and "Glaxo" on the other. They are available in bottles of 60 tablets (NDC 0173-0344-42) and unit dose packs of 100 tablets (NDC 0173-0344-47).

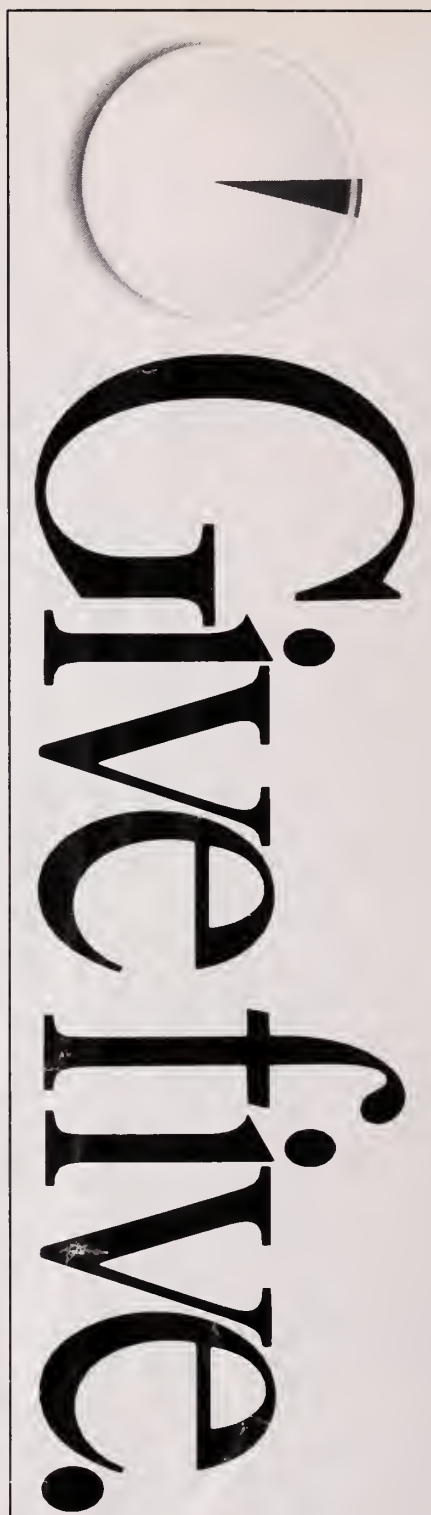
Store between 15° and 30° C (59° and 86° F) in a dry place. Protect from light. Replace cap securely after each opening.

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*Mrs. Lamar Thomas
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Auxilians in Action

The American Medical Association Education and Research Foundation (AMA-ERF) was established over 35 years ago to help support quality education in the nation's medical schools. Since 1950, the Foundation has distributed a total of over \$40 million in gifts to medical schools; guaranteed over \$95 million in loans benefiting more than 40,000 medical students, interns, and residents; and supported numerous research projects.

A-MASA is proud to have raised \$38,207.99 for AMA-ERF during 1986-87 with 80% of our county auxiliaries participating. Those counties contributing this year were: Blount, Calhoun, Coffee, Colbert, Elmore, Franklin, Geneva, Houston, Jefferson, Lauderdale, Lee, Madison, Mobile, Montgomery-Autauga, Morgan-Lawrence, Pickens, Russell, Talladega, Tallapoosa, Tuscaloosa-Hale and Walker.

The history of AMA-ERF dates back to 1950 when the AMA Board of Trustees established the American Medical Education Foundation (AMEF) for the purpose of contributing to the support of medical education. At the first meeting of the AMEF Board of Directors the following spring, it was decided to dis-

tribute gifts to medical schools through the National Fund for Medical Education (NFME), which at that time was headed by former President Herbert Hoover.

Medical schools in 1950 were reportedly operating at a deficit of \$10 million a year. The NFME and AMEF were private sector efforts to minimize the need for federal assistance to medical education. The NFME agreed to try to raise \$8 million and AMEF \$2 million to offset the deficit. The AMEF was organized specifically to raise funds from the medical community.

In 1953, the AMA Auxiliary was called on for assistance. An effective solicitation effort addressed to individual physicians was needed if AMEF was to become viable. An AMA Auxiliary AMEF Committee urged its constituent auxiliaries to become actively involved in fund-raising. Due to Auxiliary efforts, contributions from physicians and their spouses quickly grew to surpass the most optimistic predictions. AMA-ERF has, as a result, averaged gifts over \$1 million yearly ever since the Auxiliary became involved.

The AMEF separated from its association with the NFME organization in 1956. It was determined that the change might improve the fund-raising results of

both organizations. In September 1957, the American Medical Research Foundation (AMRF) was founded to encourage gifts to medical research. AMEF and AMRF were merged in 1962 to become the American Medical Association Education and Research Foundation.

AMA-ERF currently has several different funds. The Medical School Excellence Fund provides grants to medical schools to use as they see fit. The Medical Student Assistance Fund provides funds to medical schools for student financial aid. The Development Fund is used at the discretion of the AMA-ERF Board of Directors to support pilot and experimental health and medical programs. AMA-ERF also has Categorical Funds for specific research areas.

From its modest beginnings in 1950, the AMA-ERF has consistently supported quality medical education in the United States. Contributions are now more than \$2 million annually, a visible sign of medicine's continuing commitment to excellence. How is this money actually raised? The auxiliary plays a large part with numerous projects.

Holiday sharing cards are popular and effective fund-raising projects. A lovely greeting card is sent to every physician and spouse in the county with the donors names inscribed in the greeting. AMA-ERF donations are tax deductible and it is an easy and timely way to donate to the physician's alma mater. Nationwide, \$875,000 was raised last year with this fundraiser. Alabama's auxiliaries raised \$30,313 of this total.

This past year, \$2,770 was raised in Alabama through AMA-ERF Memorial cards. This is a special and thoughtful way for medical society and auxiliary members to mark the passing of a colleague, friend, or family member. The memorial card may be given to a contributor at the time it is needed or a contributor may make a donation beforehand and be given the card to keep on hand at home.

Other means employed by auxiliaries to raise money for AMA-ERF this year were raffles, auctions, Christmas Card sales and contributions.

The extraordinary fund-raising efforts of the AMA Auxiliary and the generosity of contributing medical families have secured AMA-ERF's past effectiveness and assure its future success. ■

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WARNING: Bumex (bumetanide/Roche) is a potent diuretic which, if given in excessive amounts, can lead to a profound diuresis with water and electrolyte depletion. Therefore, careful medical supervision is required, and dose and dosage schedule have to be adjusted to the individual patient's needs. (See under DOSAGE AND ADMINISTRATION in complete product information.)

INDICATIONS AND USAGE: Edema associated with congestive heart failure, hepatic and renal disease, including the nephrotic syndrome.

Almost equal diuretic response occurs after oral and parenteral administration of Bumex. If impaired gastrointestinal absorption is suspected or oral administration is not practical, Bumex should be given by the intramuscular or intravenous route.

Successful treatment with Bumex following instances of allergic reactions to furosemide suggests a lack of cross-sensitivity.

CONTRAINDICATIONS: Anuria. Hypersensitivity and in patients in hepatic coma or in states of severe electrolyte depletion. Although Bumex can be used to induce diuresis in renal insufficiency, any marked increase in blood urea nitrogen or creatinine, or the development of oliguria during therapy of patients with progressive renal disease, is an indication for discontinuation of treatment.

WARNINGS: Dose should be adjusted to patient's needs. Excessive doses or too frequent administration can lead to profound water loss, electrolyte depletion, dehydration, reduction in blood volume and circulatory collapse with the possibility of vascular thrombosis and embolism, particularly in elderly patients.

Prevention of hypokalemia requires particular attention in patients receiving digitalis and diuretics for congestive heart failure, hepatic cirrhosis and ascites, states of aldosterone excess with normal renal function, potassium-losing nephropathy, certain diarrheal states, or other states where hypokalemia is thought to represent particular added risk to the patients.

In patients with hepatic cirrhosis and ascites, sudden alterations of electrolyte balance may precipitate hepatic encephalopathy and coma. Treatment in such patients is best initiated in the hospital with small doses and careful monitoring of the patient's clinical status and electrolyte balance. Supplemental potassium and/or spironolactone may prevent hypokalemia and metabolic alkalosis in these patients. In cats, dogs and guinea pigs, Bumex has been shown to produce ototoxicity. Since Bumex is about 40 to 60 times as potent as furosemide, it is anticipated that blood levels necessary to produce ototoxicity will rarely be achieved. The potential for ototoxicity increases with intravenous therapy, especially at high doses.

Patients allergic to sulfonamides may show hypersensitivity to Bumex.

PRECAUTIONS: Measure serum potassium periodically and add potassium supplements or potassium-sparing diuretics, if necessary. Periodic determinations of other electrolytes are advised in patients treated with high doses or for prolonged periods, particularly in those on low salt diets.

Hyperkalemia may occur. Reversible elevations of the BUN and creatinine may occur, especially with dehydration and in patients with renal insufficiency. Bumex may increase urinary calcium excretion. Possibility of effect on glucose metabolism exists. Periodic determinations of blood sugar should be done, particularly in patients with diabetes or suspected latent diabetes. Patients should be observed regularly for possible occurrence of blood dyscrasias, liver damage or idiosyncratic reactions.

Especially in presence of impaired renal function, use of parenterally administered Bumex should be avoided in patients to whom aminoglycoside antibiotics are also being given, except in life-threatening conditions.

Drugs with nephrotoxic potential and bumetanide should not be administered simultaneously. Since lithium reduces renal clearance and adds a high risk of lithium toxicity, it should not be given with diuretics.

Probenecid should not be administered concurrently with Bumex.

Concurrent therapy with indomethacin not recommended.

Bumex may potentiate the effects of antihypertensive drugs, necessitating reduction in dosage.

Interaction studies in humans have shown no effect on digoxin blood levels.

Interaction studies in humans have shown Bumex to have no effect on warfarin metabolism or on plasma prothrombin activity.

Pregnancy: Bumex should be given to a pregnant woman only if the potential benefit justifies the potential risk to the fetus.

Bumetanide may be excreted in breast milk.

Pediatric Use: Safety and effectiveness below age 18 not established.

ADVERSE REACTIONS: Muscle cramps, dizziness, hypotension, headache and nausea, and encephalopathy (in patients with preexisting liver disease).

Less frequent clinical adverse reactions are weakness, impaired hearing, rash, pruritus, hives, electrocardiogram changes, abdominal pain, arthritic pain, musculoskeletal pain and vomiting.

Other clinical adverse reactions are vertigo, chest pain, ear discomfort, fatigue, dehydration, sweating, hyperventilation, dry mouth, upset stomach, renal failure, asterixis, itching, nipple tenderness, diarrhea, premature ejaculation and difficulty maintaining an erection.

Laboratory abnormalities reported are hyperkalemia, azotemia, hyperglycemia, increased serum creatinine, hypokalemia, hyponatremia, and variations in CO₂ content, bicarbonate, phosphorus and calcium. Although manifestations of the pharmacologic action of Bumex, these conditions may become more pronounced by intensive therapy.

Diuresis induced by Bumex may also rarely be accompanied by changes in LDH, total serum bilirubin, serum proteins, SGOT, SGPT, alkaline phosphatase, cholesterol, creatinine clearance, deviations in hemoglobin, prothrombin time, hematocrit, platelet counts and differential counts. Increases in urinary glucose and urinary protein have also been seen.

DOSAGE AND ADMINISTRATION:

Oral Administration: The usual total daily dosage is 0.5 to 2.0 mg and in most patients is given as a single dose.

Parenteral Administration: Administer to patients (IV or IM) with GI absorption problem or who cannot take oral. The usual initial dose is 0.5 to 1 mg given over 1 to 2 minutes. If insufficient response, a second or third dose may be given at 2 to 3 hour intervals up to a maximum of 10 mg a day.

HOW SUPPLIED: Tablets, 0.5 mg (light green), 1 mg (yellow) and 2 mg (peach), bottles of 100 and 500. Prescription Paks of 30, Tel-E-Dose[®] cartons of 100. Imprint on tablets: 0.5 mg - ROCHE BUMEX 2, 0.5, 1 mg - ROCHE BUMEX 1, 2 mg - ROCHE BUMEX 2.

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Please see adjacent page for references and summary of product information.
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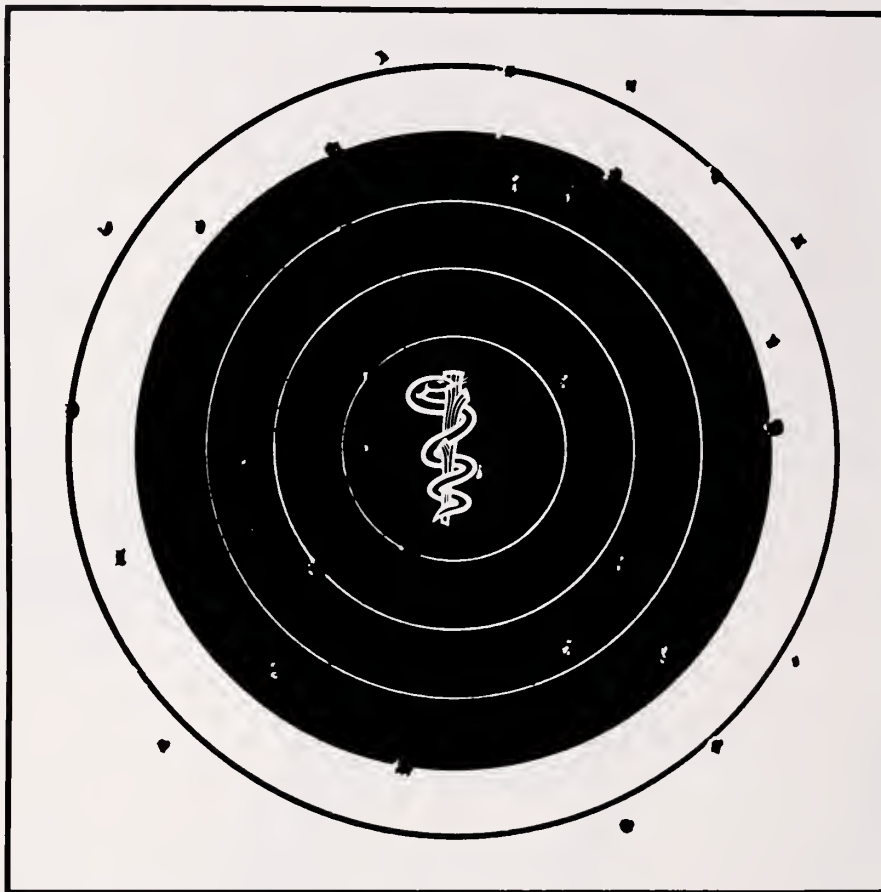
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Page 11

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The Stylebook/Editorial Manual, published by the AMA, is the general reference for questions of style. It is particularly useful in the proper presentation of data. When conflicts occur between usage, etc., by an author and the stylebook, these will be resolved in favor of the author if his method is persuasive and logical.

Helpful to many writers is *The Elements of Style* by William Strunk, Jr., and E. B. White, which emphasizes brevity, vigor and clarity.

Final authority on grammar is Webster's *New International*, Unabridged, Second Edition.

Length of Articles: Articles should not exceed 3,000 words (approximately 3-4 printed pages). Under exceptional circumstances only will articles of more than 4,000 words be published.

Illustrations: Illustrations should be numbered consecutively and indicated in the text. The number, indication of the top, and the author's name should be attached to the back of each illustration. Legend should be typed, numbered, and attached to each illustration. Photographs should be clear and distinct; drawings should be made in black ink on white paper. For photographs, glossy prints are preferred.

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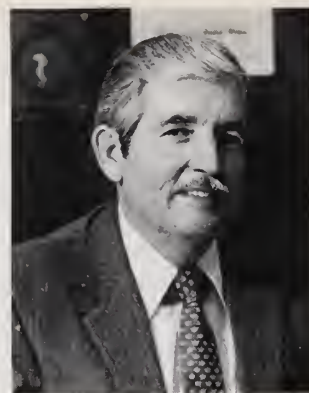


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EXECUTIVE DIRECTOR



S. Lon Conner
Executive Director, MASA

Sovietizing American Medicine?

I'm sure I am not alone in being more than a little suspicious of the highly touted Soviet *glasnost* under Mikhail Gorbachev, but there are some American authorities on the Soviet Union who say he is serious, at least about domestic reform.

As someone said, America *has* a military-industrial complex but the Soviet Union *is* a military-industrial complex. That is to say, all else in Soviet planning and in the overall objectives of the country are subordinate to its military posture. Every aspect of Russian society must support this, the principal function of any totalitarian state.

This has been true for all of the years since the Bolshevik revolution 70 years ago. But Mr. Gorbachev appears to want to change things. He has been making noises about internal reforms that will benefit the common man. High on his list of domestic changes is the Soviet health care system, a major disaster area.

No other industrialized nation, Soviet experts say, would tolerate what the people of U.S.S.R. are forced

to accept in their collectivized health care system. More than a third of the rural hospitals in the country don't have such basic amenities as hot water; 27% of them have no sewer systems, if you can believe that; and 17% have no running water.

The city hospitals are only marginally better off. For example, 12 of 33 maternity hospitals in Moscow itself don't meet elementary standards of sanitation. The maternity wards are rife with toxemia and septicemia infections, killing so many mothers and babies that it has been necessary to conceal mortality rates.

That is, in fact, the way the Soviet Union has deceived their own people and the world about the status of Soviet health: officials simply lie about it.

For example, the U.S.S.R. has long boasted of having the world's largest number of physicians (1.2 million) and hospital beds (3.3 million). Even if the count is accurate, however, it is virtually meaningless. Many of those beds are in various levels of penal institutions for political dissidents. Additionally, many Soviet

physicians prefer the better paying and easier work of the bureaucracy, including paper-shuffling in 333 Soviet "research institutions." A third of these could be closed tomorrow without visible effect, according to authorities on the system.

An unknown number of Soviet doctors hold government jobs while practicing private medicine on the black market: they accept "gratuities" for the services, taboo in a collectivized communist society.

A basic problem of the Soviet doctors is that the Bolshevik revolution of 1917 abolished the Hippocratic Oath, for the obvious reason that it places a physician's loyalty to his patient above all else. That remains intolerable in a totalitarian state, which demands that all fealty be directed to it.

It was not until 1971 that Soviet doctors had any kind of official oath, and here is the first point of this month's essay: that 1971 oath extracts from the physician primary loyalty to the state. The patient comes in a weak second.

Is there any wonder then that health care for the Soviet masses has fallen to such a low estate? Doctors are expressly forbidden to practice patient advocacy. As in many other areas of Soviet life, vast inequalities exist despite the ostensible equality of it all. Health care in the U.S.S.R. is divided into multiple tiers, with a network of exclusive nationwide clinics that serve only patients from the Communist Party, the government, members of the KGB and other privileged classes. These clinics, needless to say, siphon off a disproportionate share of total health care resources. Such elitism is, of course, not acknowledged by the government.

What troubled me most in reading all of this recently was that feeling that something frighteningly similar may be happening in this country. Doctors are being asked by government and all manner of private entities to place the interest of the state or other fiscal entity above that of the patient. Business-office mandates are rapidly replacing medical judgment. The government and other third-party payors pretend to be interested in quality of care but their paramount interest is in limiting *quantity* of care. They never admit that, of course.

Through various mechanisms, the United States is developing multiple tiers of care — from excellent to highly questionable — not unlike the Soviet system. And here, as there, the Hippocratic Oath has been diluted by cost-accounting strictures, to the extent that the patient's interests are rapidly becoming secondary, as they are in Soviet society, although we certainly have not reached that depth yet. To paraphrase George Orwell's famous fable on phony equality: "All patients are equal but some are more equal than others."

Mr. Gorbachev seems determined to bring about "revolutionary transformations" in Soviet health care and has demonstrated his determination by appointing as his new minister of health Dr. Yevgeny Chazov, a cardiologist respected in the West and co-winner of the 1985 Nobel Peace Prize.

Since his appointment in March, Dr. Chazov has revealed one outrageous statistic after another to demonstrate the sorry state of Soviet medicine. In his proposal to double Soviet spending on health care by the year 2000, Dr. Chazov is reported to be considering a funding mix that would include collections from patients — in short, fee for service.

It strikes me as supreme irony that at the very moment in history when American health care is being severely compromised by disguised rationing and the drift to collectivization, the Soviet Union may be headed in the opposite direction — toward the system America is trying to dismantle.

I take very little comfort in the assurance that it can't happen here. It can. ◻

Lon



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CALL FOR PAPERS

Medical Association of the State of Alabama FOURTH INVITATIONAL SCIENTIFIC SYMPOSIUM

Saturday, January 23, 1988 — 9 a.m. to 4 p.m.
The Wynfrey Hotel, Riverchase Galleria, Birmingham

Purpose of the Program — This program is designed to allow Alabama physicians to share with their colleagues current research efforts and professional concerns. Topics selected will cover a wide range of medical interests.

Program Format — The program will be structured from the papers submitted by Alabama physicians. Depending on the number of papers received, topics, etc., some papers will be presented orally while others may be part of a manuscript discussion period led by a moderator. Registrants and participants will receive advance copy of all papers.

Paper Selection — Papers will be selected using the following criteria and procedures.

1. The subject matter should be of interest to physicians in a number of specialties. Emphasis should be on medical problems which may be encountered by primary care physicians.
2. This is a program designed for and presented by Alabama physicians, so current local research efforts and professional concerns will be given top consideration.
3. The paper should be one that can be adequately outlined and covered in 20 minutes with additional time for questions. Selectees will be expected to prepare suitable written material to be used with the presentation for the study and use of the attendees.
4. On the final review of papers, members of the MASA Council on Medical Education will select topics from a variety of specialties and physician interests to offer a balanced program of general interest.

Symposium Timetable . . . August 15 to October 15, 1987 — Call for abstracts. October 15, 1987 — Final date for abstracts to be received. Late October, 1987 — Review of abstracts by the Council on Medical Education and final selection of papers. November-January 1988 — Announcement of selections; publicity and promotion of Symposium, printing of abstracts and handouts. January 23, 1988 — Program in Birmingham.

Symposium Topics — To acquaint potential presentors with the kinds of subjects that might be suitable, the speakers and topics at the 1986 Symposium are listed below.

Robert L. Baldwin, M.D. — **Current Concepts Regarding Hearing Loss and Its Therapy**; S. Hutson Hay, M.D. — **Photography in the Detection of Eye Disease in Children**; William M. Sanders, M.D. — **Psychiatric Referral of the Difficult Patient**; David L. Rader, M.D. — **Lasers in Medicine and Surgery**; Charles W. Pruet, M.D. — **Common Departures from Sound Management in Head and Neck Cancer**; R. Jay Smith, M.D. — **The Spectrum of Surgical Therapy for Primary Carcinoma of the Breast**; Carl J. Sanfelippo, M.D. — **Prostate Cancer — Current Concepts and Managements**; Gary D. Monheit, M.D. — **The Moh's Technique: Micrographic Surgery for Problem Skin Cancer**; Richard D. Meyer, M.D. — **Obstetrical Palsy, Current State of the Art**; Roger W. Boswell, M.D. — **Acute Care and Chronic Medical Illness**; Larry W. Epperson, M.D. — **Treatment of Vascular Headaches**; Thomas Gaskin, M.D. and Bruce Tucker, M.D. and Linda Zwirlein, R.N., M.S. — **Home Parenteral Therapy**; John L. Mathews, M.D. — **Retrospective Review of Permanent Pacemakers**; Rudolph Navari, M.D., Ph.D. — **Use of Biological Response Modifiers in Treatment of Cancer**.

Abstracts — Abstracts of the proposed paper (200-300 words, double-spaced) should be sent to the Council on Medical Education, using the form below, or a similar format.

ABSTRACT

TO: Council on Medical Education, MASA, P.O. Box 1900-C, Montgomery, AL 36197

I would like to present a paper at the MASA Invitational Symposium on Saturday, January 23, 1988 at the Wynfrey Hotel in Birmingham. An abstract (200-300 words double-spaced) is attached.

I would like to be considered for:

- ☐ Oral presentation of complete paper only
☐ Either oral presentation or manuscript discussion period
☐ Manuscript discussion period only

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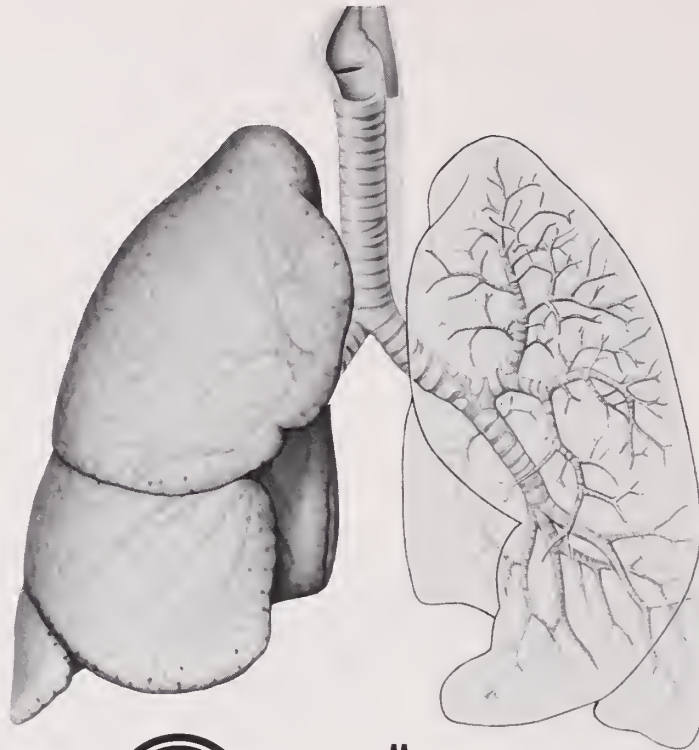


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Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. See prescribing information.

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Summary. Consult the package literature for prescribing information.

Indications: Lower respiratory infections, including pneumonia, caused by susceptible strains of *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Streptococcus pyogenes* (group A β -hemolytic streptococci).

Contraindication:
Known allergy to cephalosporins.

Warnings:

CECLOR SHOULD BE ADMINISTERED CAUTIOUSLY TO PENICILLIN-SENSITIVE PATIENTS. PENICILLINS AND CEPHALOSPORINS SHOW PARTIAL CROSS-ALLERGENICITY. POSSIBLE REACTIONS INCLUDE ANAPHYLAXIS.

Administer cautiously to allergic patients. Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics. It must be considered in differential diagnosis of antibiotic-associated diarrhea. Colon flora is altered by broad-spectrum antibiotic treatment, possibly resulting in antibiotic-associated colitis.

Precautions:

- Discontinue Ceclor in the event of allergic reactions to it.
- Prolonged use may result in overgrowth of nonsusceptible organisms.
- Positive direct Coombs' tests have been reported during treatment with cephalosporins.
- Ceclor should be administered with caution in the presence of markedly impaired renal function. Although dosage adjustments in moderate to severe renal impairment are usually not required, careful clinical observation and laboratory studies should be made.
- Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.
- Safety and effectiveness have not been determined in pregnancy, lactation, and infants less than one month old. Ceclor penetrates mother's milk. Exercise caution in prescribing for these patients.

Adverse Reactions: (percentage of patients)

Therapy-related adverse reactions are uncommon. Those reported include:

- Gastrointestinal (mostly diarrhea): 2.5%.
- Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment.
- Hypersensitivity reactions (including morbilliform eruptions, pruritus, urticaria, and serum-sickness-like reactions that have included erythema multiforme [rarely, Stevens-Johnson syndrome] or the above skin manifestations accompanied by arthritis/arthralgia and, frequently, fever): 1.5%; usually subside within a few days after cessation of therapy. Serum-sickness-like reactions have been reported more frequently in children than in adults and have usually occurred during or following a second course of therapy with Ceclor. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome.
- Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy.
- As with some penicillins and some other cephalosporins, transient hepatitis and cholestatic jaundice have been reported rarely.
- Rarely, reversible hyperactivity, nervousness,

insomnia, confusion, hypertonia, dizziness, and somnolence have been reported.

- Other: eosinophilia, 2%; genital pruritus or vaginitis, less than 1%; and, rarely, thrombocytopenia.

Abnormalities in laboratory results of uncertain etiology

- Slight elevations in hepatic enzymes.
- Transient fluctuations in leukocyte count (especially in infants and children).
- Abnormal urinalysis; elevations in BUN or serum creatinine.
- Positive direct Coombs' test.
- False-positive tests for urinary glucose with Benedict's or Fehling's solution and Clinitest[®] tablets but not with Tes-Tape[®] (glucose enzymatic test strip, Lilly).

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Carl A. Grote, Jr., M.D.
President, MASA

MASA's Tentative AIDS Policy

At the August meeting of the Board of Censors, MASA adopted an AIDS policy statement based on present knowledge about this deadly disease.

Below is the full text of that policy. When reading it, please bear in mind that scientific knowledge about AIDS is far from complete. Accordingly, the Board left the policy open-ended — it will be revised as new information warrants.

MASA's Policy on AIDS

The AIDS epidemic worldwide could be the most disastrous in recorded history, according to expert opinion.

Surgeon General Koop has said the international death toll in a few years is expected to be in the tens of millions.

Harvard's famous Stephen Jay Gould has written that among scientists there is the fear that one-quarter of mankind — or more than *one billion people* — may perish before stability is reached.

AIDS has replaced cancer and heart disease as the No. 1 fear of the American people, pollsters agree.

Tentative projections by Alabama's State Health Of-

ficer suggest that one out of every fourteen Alabamians will carry the HIV virus by 1991. Their direct health care costs will be \$150 million with a total cost to Alabama society of \$750 million.

AIDS is a fatal illness. No vaccine or immediate prospect of one exists. There is no cure, notwithstanding millions of man-hours of work in the research laboratories of the world. The very nature of the invasion of the immune system by the AIDS virus offers little hope of vaccine protection or effective therapeutic intervention in the foreseeable future.

In short, medical science is now in a damage-control mode only. As weapons are produced by the laboratories, medicine will move from the defensive to the offensive, but only then.

Alabama physicians have a long and honored history of aggressive confrontation of epidemics, even when neither cause nor cure was known — as witness the world renown accorded or professional predecessors in the wars against yellow fever, malaria and other epidemics. They did not hesitate simply because the disease was mysterious and catastrophic and no cure existed.

Public alarm is justified; hysteria is not.

Alabamians have a right to know that their physicians have accepted the leadership role in protecting citizens of this state to the maximum extent possible under current knowledge, with due regard to our system of law and justice.

The Board of Censors of the Medical Association of the State of Alabama offers the following recommendations to Alabama physicians, the public at large, and appropriate public officials. These recommendations are based on current knowledge and belief, to be revised and updated as new scientific information is adduced and/or circumstances dictate:

1. Leadership and Education

A. Alabama physicians must take a leadership role in persuading local school districts to adopt effective programs of AIDS information for Alabama youth. Abstinence leading to monogamous relationships in later life should be stressed as the only course that offers complete security against AIDS. But the sexual revolution is real and widespread — far more so than many parents or teachers are prepared to believe. An ostrich approach to the problem will only compound the disaster. Sex education programs in the public schools should be derived from the model program being made available by the State Health Officer. If society chooses to look the other way and hope it doesn't happen here, it will happen here. It is already happening here. The penalty for failure of mass education is not an inconvenient illness, but death.

B. To provide the leadership demanded by these critical times, Alabama doctors must be themselves educated in the facts of the disease, which could not have been covered in the training of more than a handful of state physicians. Doctors must also avail themselves of the techniques of counselling before and after testing, giving particular stress to advising patients who test positive for HIV. In many instances, the physician will be society's first line of defense against an infected person's transmission of the disease to others. Interrupting the chain of transmission as early as possible is plainly crucial.

C. The Alabama communications industry should develop its own voluntary guidelines for news stories and public service advertising (PSA) in consultation with the physician community, local and state health officers, and other appropriate officials. AMA is expected to continue its provision of PSAs directed at teenagers, emphasizing abstinence first but, failing that, condoms. Similar action by the Medical Association of the State of Alabama is appropriate in Alabama.

2. Confidentiality

A. Because AIDS is a public health emergency, the likes of which mankind has never before encountered, some civil liberties that could have been observed in

calmer times must necessarily bend to the exigencies of the emergency and to the paramount duty of public health to protect the uninfected portion of the population. Confidentiality should be maintained in so far as practicable, given the necessity of contact-tracing, discussion among other health workers, and given the possibility that a physician may be under duty to warn — all of which duties transcend the rights of the victim. It must be remembered that this is a lethal disease, without vaccine or cure, and that the *victim is the vector*. Compassion for HIV patients must not blind us to the need to protect the general population. We see no reason to depart from the proven methods of disease containment that have served this nation well in past epidemics, including quarantine if indicated.

3. Testing

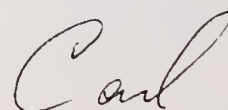
A. Testing should be mandatory in the state prison system and, perhaps, in those city and county jails where inmates are sentenced to a term of incarceration. HIV positive inmates should be rigidly segregated from the rest of the inmate population. When HIV positive inmates are released from prison, through completion of sentence, pardon and parole, or short-term, prison authorities must have in readiness an effective mechanism for warning sexual partners.

B. Testing for HIV should be mandatory for donors of blood, blood fractions, organs and other tissue intended for transplantation, for donors of semen or ova collected for artificial insemination or invitro fertilization.

C. The mandatory testing of all hospital admissions may not be an important method of controlling HIV infection. However, some hospitals may elect to test some or selected admissions/pre-admissions based upon risk status, demographic location or other concerns (for example, those patients scheduled for surgery, or other invasive procedures).

D. The State Health Department has plans for programs of voluntary AIDS testing in its clinics for venereal diseases, family planning, and maternity. A ten-fold increase in testing using these in-place facilities is contemplated under the Health Officer's request for \$1.9 million in additional state funding — a legislative request that must be forthcoming if the state is to succeed in better identification of the infected portion of the population.

E. Physicians must promptly report such cases as are required to be reported by law. Prompt and accurate reporting is necessary so that the Health Department can implement contact tracing and counselling. □



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Because those women won't practice breast self-examination regularly.

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Life is just too wonderful to give up on. And, as I found out, you don't have to give up on any of it. Not work, not play, not even romance.

Oh, there is one thing, though.

You do have to give up being afraid to take care of yourself.



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The Unmentionable, Charity Care

Carl A. Grote, Jr., M.D., President, MASA

Dear Carl:

I read with considerable interest your "Orphans of the Storm" in the June issue of *Alabama Medicine*. Of what you write, I have seen coming down the road for over a generation.

I have sought through my County Society to have MASA adopt resolutions directed towards elements in the fundamental problem. The problem is so simple that learned physicians cannot understand it. Essentially wealth is production. The best proof is Japan, today.

Wealth minus consumption equals plus-or-minus savings. Minus savings must be made up in a macroeconomic system by the reduction of accumulated wealth. Time destroys wealth a little bit each year. Roads wear out, capital investments corrode and erode, wood rots, housing decays, and practically everything is reduced in value over time, except precious metals.

With the previous in mind, one can readily see that the U. S. economy must increase its production, reduce its consumption, increase the rate of savings, and thus increase the pool of national wealth. One of the greatest factors in increasing production is the employment of more efficient tools. The tools of production are expensive, require great wealth, and are poorly understood in an economic sense. For example, a diesel power shovel may do the work of 50 to 100 men, but the shovel costs a million dollars or more plus interest and operating expense. Only accumulated wealth can supply the shovel.

In the United States we have been at the crossroads, and I fear that we have passed our economic peak. Under these circumstances there will be increasing pressure of various segments of society to obtain an ever diminishing slice of the economic pie. Health care is just one of many hundreds of demands, all of which are expressed as good, beneficial, just, right, needed, and any other expression that you can think of.

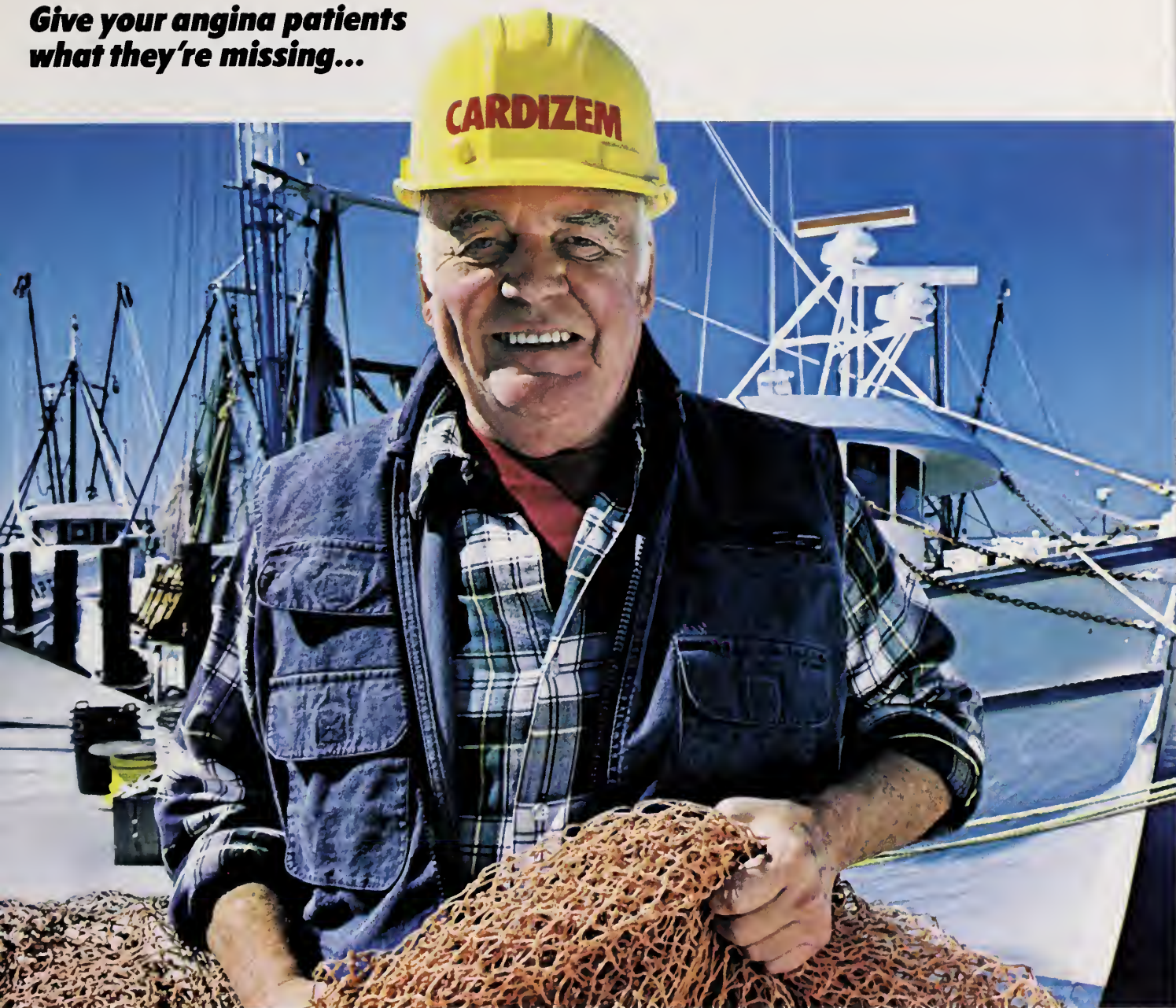
Somewhere there will have to be rationing of one sort or another. This is painful, unpopular, but a fact! One of the results of this fact "uncompensated care" will be termed what historically it was called, ie, "charity care." Uncompensated care came as a result of the idea that everyone was to have the same high level of care. This phantom idea has had as one of its major proponents the organized medical profession of our state and nation.

There is nowhere evidence, based upon economics, politics or constitutional law that this ephemeral concept will endure. The idea that every person will live forever, enjoy the pinnacle of modern scientific health care and that this care will and can be supported by "someone," is fundamentally false. You simply have to go back to the fundamental economic equation given in the first of this letter.

Therefore, the sooner we use the proper language, ie, charity care, and the sooner we approach it for what it is, the sooner the problem will become manageable.

J. P. Mudd, Jr., M.D.
Jackson, AL

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Brief Summary Professional Use Information

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CONTRAINDICATIONS

CARDIZEM is contraindicated in (1) patients with sick sinus syndrome except in the presence of a functioning ventricular pacemaker, (2) patients with second- or third-degree AV block except in the presence of a functioning ventricular pacemaker, and (3) patients with hypotension (less than 90 mm Hg systolic).

WARNINGS

- Cardiac Conduction.** CARDIZEM prolongs AV node refractory periods without significantly prolonging sinus node recovery time, except in patients with sick sinus syndrome. This effect may rarely result in abnormally slow heart rates (particularly in patients with sick sinus syndrome) or second- or third-degree AV block (six of 1,243 patients for 0.48%). Concomitant use of diltiazem with beta-blockers or digitalis may result in additive effects on cardiac conduction. A patient with Prinzmetal's angina developed periods of asystole (2 to 5 seconds) after a single dose of 60 mg of diltiazem.
- Congestive Heart Failure.** Although diltiazem has a negative inotropic effect in isolated animal tissue preparations, hemodynamic studies in humans with normal ventricular function have not shown a reduction in cardiac index nor consistent negative effects on contractility (dp/dt). Experience with the use of CARDIZEM alone or in combination with beta-blockers in patients with impaired ventricular function is very limited. Caution should be exercised when using the drug in such patients.
- Hypotension.** Decreases in blood pressure associated with CARDIZEM therapy may occasionally result in symptomatic hypotension.
- Acute Hepatic Injury.** In rare instances, significant elevations in enzymes such as alkaline phosphatase, CPK, LDH, SGOT, SGPT, and other symptoms consistent with acute hepatic injury have been noted. These reactions have been reversible upon discontinuation of drug therapy. The relationship to CARDIZEM is uncertain in most cases, but probable in some. (See PRECAUTIONS.)

PRECAUTIONS

General. CARDIZEM (diltiazem hydrochloride) is extensively metabolized by the liver and excreted by the kidneys and in bile. As with any new drug given over prolonged periods, laboratory parameters should be monitored at regular intervals. The drug should be used with caution in patients with impaired renal or hepatic

function. In subacute and chronic dog and rat studies designed to produce toxicity, high doses of diltiazem were associated with hepatic damage. In special subacute hepatic studies, oral doses of 125 mg/kg and higher in rats were associated with histological changes in the liver which were reversible when the drug was discontinued. In dogs, doses of 20 mg/kg were also associated with hepatic changes; however, these changes were reversible with continued dosing.

Drug Interaction. Pharmacologic studies indicate that there may be additive effects in prolonging AV conduction when using beta-blockers or digitalis concomitantly with CARDIZEM. (See WARNINGS.)

Controlled and uncontrolled domestic studies suggest that concomitant use of CARDIZEM and beta-blockers or digitalis is usually well tolerated. Available data are not sufficient, however, to predict the effects of concomitant treatment, particularly in patients with left ventricular dysfunction or cardiac conduction abnormalities. In healthy volunteers, diltiazem has been shown to increase serum digoxin levels up to 20%.

Carcinogenesis, Mutagenesis, Impairment of Fertility. A 24-month study in rats and a 21-month study in mice showed no evidence of carcinogenicity. There was also no mutagenic response in *in vitro* bacterial tests. No intrinsic effect on fertility was observed in rats.

Pregnancy. Category C. Reproduction studies have been conducted in mice, rats, and rabbits. Administration of doses ranging from five to ten times greater (on a mg/kg basis) than the daily recommended therapeutic dose has resulted in embryo and fetal lethality. These doses, in some studies, have been reported to cause skeletal abnormalities. In the perinatal/postnatal studies, there was some reduction in early individual pup weights and survival rates. There was an increased incidence of stillbirths at doses of 20 times the human dose or greater.

There are no well-controlled studies in pregnant women; therefore, use CARDIZEM in pregnant women only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers. Diltiazem is excreted in human milk. One report suggests that concentrations in breast milk may approximate serum levels. If use of CARDIZEM is deemed essential, an alternative method of infant feeding should be instituted.

Pediatric Use. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Serious adverse reactions have been rare in studies carried out to date, but it should be recognized that patients with impaired ventricular function and cardiac conduction abnormalities have usually been excluded.

In domestic placebo-controlled trials, the incidence of adverse reactions reported during CARDIZEM therapy was not greater than that reported during placebo therapy.

The following represent occurrences observed in clinical studies which can be at least reasonably asso-

ciated with the pharmacology of calcium influx inhibition. In many cases, the relationship to CARDIZEM has not been established. The most common occurrences as well as their frequency of presentation are: edema (2.4%), headache (2.1%), nausea (1.9%), dizziness (1.5%), rash (1.3%), asthenia (1.2%). In addition, the following events were reported infrequently (less than 1%):

Cardiovascular:	Angina, arrhythmia, AV block (first degree), AV block (second or third degree — see conduction warning), bradycardia, congestive heart failure, flushing, hypotension, palpitations, syncope.
Nervous System:	Amnesia, gait abnormality, hallucinations, insomnia, nervousness, paresthesia, personality change, somnolence, irritability, tremor.
Gastrointestinal:	Anorexia, constipation, diarrhea, dyspepsia, dyspepsia, mild elevations of alkaline phosphatase, SGOT, SGPT, and LDH (see hepatic warnings), vomiting, weight increase.
Dermatologic:	Petechiae, pruritus, photosensitivity, urticaria.
Other:	Amblyopia, dyspnea, epistaxis, eye irritation, hyperglycemia, nasal congestion, nocturia, osteoarthralgia, pain, polyuria, sexual difficulties.

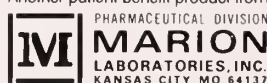
The following postmarketing events have been reported infrequently in patients receiving CARDIZEM: alopecia, gingival hyperplasia, erythema multiforme, and leukopenia. However, a definitive cause and effect between these events and CARDIZEM therapy is yet to be established.

Issued 9/86

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Persistence

Ucello, M.D.*

Press On

Nothing in the world can take the place of persistence. Talent will not: nothing is more common than unsuccessful men with talent. Genius will not: unrewarded genius is almost a proverb. Education alone will not: the world is full of educated derelicts. Persistence and determination alone are omnipotent.

One should always try to keep up with the literature. Recently I was perusing an issue of *Today's Chiropractic*, and I ran across an article eulogizing a recently deceased eminent New York chiropractor, Doctor (sic.) Lyndon E. Lee.¹ Dr. Lee, the article says, "next to B. J. Palmer himself . . . may have been the most quoted chiropractor of his time."

His "first published defense of chiropractic appeared in the scholarly *Harper's Weekly*" in 1915. In 1933 he was arrested in New York for practicing medicine without a license. The case dragged on for more than three years and was in and out of courts 30 times. The trials attracted national attention, and he received much support; e.g., from an editorial in *Nation's Commerce*. He was finally acquitted.

Thirty years later in 1963 a bill providing for the licensure of chiropractors in New York state became law, and Dr. Lee, age 77, sat for and passed the first

examination by the New York State Board of Chiropractic Examiners. This so impressed the political hierarchy that Governor Nelson Rockefeller expressed his admiration for Dr. Lee.

In 1981 the Smithsonian Institution of Washington, D.C., sponsored "the first Conference on Chiropractic History," and there the Association for the History of Chiropractic named him the recipient of its first honorary award.

In 1983 Dr. Lee died in his sleep, just one week short of his 96th birthday having "led the chiropractors of New York in their half-century struggle for licensure" in that state.

The eulogy in *Today's Chiropractic* says that his death "wrote a finish to one of the more remarkable personal histories in the annals (sic.) of the chiropractic profession." He graduated from the Palmer School in 1915 and "helped draft every licensing bill presented to the (New York) legislature between 1915 and 1963, when a favorable vote was finally obtained."

He had attended an ivy league college, Amherst, so presumably had a good basic college education. Why did he attend chiropractic college? One can only speculate, though the article mentions that his brother (an older brother?) was also a chiropractor. Probably the course of study required only one year or less, and this occurred as the Flexner reform was gaining momentum and medical schools were closing or being upgraded. His son, who was a friend of mine, was a physician (M.D.) and a surgeon well known through-

* Ucello, M.D. is a pseudonym for a physician practicing in Alabama.

out the nation, which is why the article caught my eye.

The point of the story, however, is PERSISTENCE. The United States these days is being assaulted by a vast and heterogeneous army of "health care professionals" — physicians with M.D.s, physicians with D.O.s, others who want to call themselves "physicians" (we should protect this term as belonging to the M.D.s alone, if at all possible), doctors of pharmacy, doctors of podiatry, doctors of optometry, doctors of nursing, doctors of naturopathy, doctors of naprapathy, doctors of chiropractic, doctors of counselling, on and on.

This is the real doctor glut. All are trying to emulate M.D.s to the extent of tapping the third-party payors who have contributed so much to the current wealth of many "health care professionals," especially physicians. And many are intelligent, probably helpful to most of their patients, and very, very persistent in their efforts at legal and economic recognition. Dr. Lee, after all, kept introducing bills into the New York legislature for 49 years, until one was passed, 1915 to '63 inclusive.

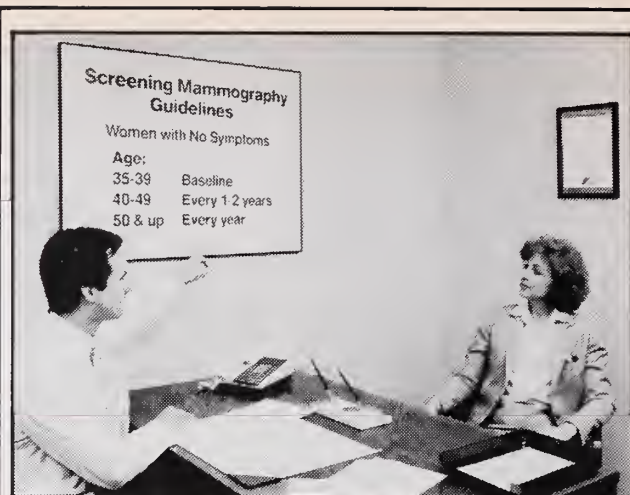
The moral for M.D.s is: If they can persist, so can we. If they can pass laws, so can we.

MASA has just concluded, at least for the time being, a successful campaign for tort reform that many thought was unwinnable. If the "other health care professionals" persist in attempting to win for their lesser trained groups the legal right to engage in activities that we believe should be reserved for those who are most rigorously, thoroughly, and completely educated and trained for those activities — the M.D.s, it is indeed our duty to persist in efforts to resist them and to roll back their legislative advances. ■

PERSIST!

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What will you tell her about screening mammography?

Many of your patients will hear about screening mammography through a program launched by the American Cancer Society and the American College of Radiology, and they may come to you with questions. What will you tell them?

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Senior Medical Students In Guatemala

Foreword

The feeling of elation that comes with advancement into the senior year of the College of Medicine is so exhilarating that it must be experienced for maximum appreciation. In reality there is something lacking in those nine months of that final year in medical school besides the self-assurance of graduation.

Many weeks and months are spent by students surveying postgraduate facilities. Possibly something worthwhile is to be gained from a first-hand visitation. Five years may be spent at a hospital in a phase of advanced medical training before entering the private sector or the academic world of medicine. How many facilities should a student visit? How long should all the visitations require?

Senior electives might be limited to one or two "free electives" of four-weeks duration. The remainder could more profitably be devoted to assignment as an acting intern in any one of the specialties that appeals to the student. Some unique learning experience remote to the College from which graduation is anticipated could be included in the final year's program.

As a fulfilling experience and one which has been envisioned as a unique learning opportunity, the University of South Alabama College of Medicine offers a Senior Elective: *Rural and Tropical Medicine in a Developing Nation*. Here the student is exposed to new disease entities. The diagnostic and therapeutic modalities are totally different from almost anything found in the medical world of our United States.

Letters which our students have written following four weeks in Guatemala in our exchange program with Marroquin University School of Medicine convey their response to an unforgettable Senior Elective. They are published with the envisionment of your sharing with me the consideration for curriculum changes in the Senior year at the various Colleges of Medicine.

Samuel Eichold, M.D.
Professor Emeritus
University of South Alabama
College of Medicine

Trip Report — I

“‘**M**ucho Gusto’” became an often heard phrase that I not only learned but used frequently during my trip to Guatemala during February of 1987. It seemed only a dream last March when my colleague, Niki Oquist, and myself received information and signed up for an externship rotation as fourth year medical students.

The curriculum that the University of South Alabama College of Medicine for fourth year students has many opportunities for expanding our medical knowledge, but most interesting to us seemed to be one entitled “Rural and Tropical Medicine in a Developing Nation.”

After discussing it between ourselves we then contacted the faculty advisor for the rotation, Dr. Samuel Eichold, professor emeritus, at the University of South Alabama College of Medicine, who informed more about the rotation and past experiences of students in Guatemala.

“Rural and Tropical Medicine in a Developing Nation” was in rotation set up by Dr. Eichold in conjunction with a long-time friend, Dr. Rodolfo Herrera-Llerandi, as an exchange program with medical students from the University of South Alabama College of Medicine in Mobile, Alabama and students from the Universidad of Francisco Marroquin in Guatemala City.

Until last year only students from the Universidad of Francisco Marroquin had taken advantage of the rotation. Last year two students Chuck Schroll and Roy Sanders, from the University of South Alabama College of Medicine went to Guatemala and came back with some interesting tales told to us by Dr. Eichold.

By November of 1986, Niki and I had begun to formalize our plans and learned that two other University of South Alabama College of Medicine students were going to be with us in Guatemala, Debbie Campbell and Lisa Wright. All of us were quite anxious for several reasons, especially because of the language barrier.

Niki, who had lived most of his life in Latin America, agreed to teach us and tutor us in Spanish which proved to be invaluable after we had arrived in Guatemala. By December we had all begun to listen to Spanish tapes and held practice sessions together. At that time Niki and I had also contacted the Partner of the Americas program for hopeful assistance in travel

expenses. By mid-January 1987 everything was set and on Feb. 7, 1987 we departed from Mobile to New Orleans then on to Miami and then finally to our destination in Guatemala City.

We were met at the airport in Guatemala City by long time friend of Niki and his family, Lorenzo Figueroa. He took us to his home, where we met his more than gracious family and obtained details on our housing arrangements which had been settled by him. We would stay at an apartment in the home of his wife's sister and as well he set us up with some invaluable transportation. Without Lorenzo and the Figueroa family, our experiences in Guatemala would not have been as colorful as it was.

On March 9, 1987 we met with Dr. Rodolfo Lorenzana at the Hospital Herrera Llerandi and Universidad Francisco Marroquin Medical School. He is the dean of medical students at the University as well as a pathologist at the Hospital Herrera Llerandi and the Roosevelt Hospital in Guatemala City. As the main person in charge of us over the next four weeks, he had arranged a tentative schedule for us. The first week we were to spend in a general clinic behind the Hospital Herrera Llerandi. The next two weeks we would be out in the rural areas or highlands, the last week was open for us to visit other areas of interest. He then took us to the clinic and introduced us to the Clinic Chief Romeo De Leon.

At the clinic, we met the staff which consisted of several medical students, residents, and specialty attendings. We also had a tour of two very contrasting hospitals in Guatemala. First, the Hospital Herrera Llerandi, which was much like hospitals in the United States, then the Roosevelt Hospital which lacked many supplies taken for granted by staff people of United States hospitals.

The next two weeks at the highlands were extremely informative. The rural network, headed by Dr. Carlos Andrade, in the villages around San Juan Sacatepequez provided a better understanding of the importance of preventive medicine and primary health care. In the past decade of record collecting around San Juan, more than 90% of the mortality consisted of preventable diseases. With the advent of education to the natives on good health habits, instituting programs for vaccinations, and even more importantly good prenatal care there could be a drop in the morbidity and mor-

tality statistics in these areas.

We worked along with two other medical students, Patty and Juan Carlos, who reported to the area at the same time we did. There was also a staff physician, Dr. Jorge Palacios, who also oversaw the rural operations, who came to the areas on Wednesdays. Since it was not well known to the natives that the clinic was staffed on other days besides Wednesdays, some days seemed quite slow only with occasional house calls. However, this gave us ample time to share informative information on medical training and treatment philosophies as well as cultural differences between our two nations.

I guess it came as no surprise to me in an area where there was only running water for two hours every other day the problems the natives had in keeping good health. Financially the natives in the village who specialized in making bamboo baskets and rope could not afford the treatments for their illnesses so they often went without therapy.

Under the direction of Dr. Palacios, several town members were being taught the cardinal manifestations of preventable diseases and acute trauma therapy. Also a program to educate many midwives at the villages on prenatal, partum, and postpartum care in hopes to lower maternal and infant mortality which was extremely large for the population. Programs were also set up for vaccinations and nutritional education. The only regret that we had in this area was that the students in the area were just as new to the program as we were, therefore a lot of the time seemed wasted on not knowing what to do or where to go.

The final week we remained in Guatemala City and toured some of the private clinics and investigated more of the local hospitals. All in all I found the trip had a great impact on my thinking and what I had taken for granted in Mobile was not often available in

all areas. I met a long list of extremely nice hospital people who opened their arms and doors to make sure that I learned as much as possible during my stay in Guatemala.

The travel set up by the Partners of the Americas Association was very much appreciated. Many thanks to the Partners Association for their help in making the trip and experience possible. Of course we found our own accommodations in Guatemala City with the help of a friend and everything seemed to work out well for all involved. I have now found a new and exciting place that I can't wait to return to.

As far as future exchange programs go, I think that there is still a lot that can be done. First, I don't recommend the externship to anyone who doesn't know someone in Guatemala City. Without the Figueroa family's help we would have been lost without room or transportation. Second, I would not encourage anyone without a decent understanding of Spanish to try to venture into Latin America unless you know a reliable guide. Lastly, I think that we lost a lot by going to the highlands before the system was set up to function the way it was intended.

In conclusion, if the following criteria are met visiting students and the partnership between Guatemala and Alabama as well as the University of South Alabama College of Medicine and the medical school at the Universidad of Francisco Marroquin, will benefit the most from the program. Through the findings of my trip I now realize that there is so much beyond the United States of America. I can only anxiously await until I visit another new land or return to a newly found land and share it with other newcomers.

Russell Alan Hudgens
MS-IV

Trip Report — II

Rodolfo Lorenzana, M.D.
Universidad Francisco Marroquin
Facultad de Medicina
6a. Avenida 7-55, Zona 10
Guatemala, Guatemala C.A.

Dear Dr. Lorenzana:

I want to express to you my sincere appreciation for the opportunity of a lifetime. Living and working for that short time in Guatemala was both an invigorating

medical and personal experience. I became exposed not only to interesting medical cases, but became integrated into the Latin American culture.

At the University of South Alabama College of Medicine we work in only one hospital in the city of Mobile. Any chance to observe and participate in patient care at a different institution is a welcome opportunity to broaden my clinical experience. With that in mind, I traveled to Guatemala with eager anticipation.

Arriving at the Francisco Marroquinn University, I

found that every faculty member and student that I came in to contact was extremely friendly and helpful to their foreign guests. It was particularly enjoyable to exchange experiences with the medical students who were at the same level of training and to discover the differences as well as many similarities in medical education.

The first week of our rotation was spent at the clinica Departamento "E" where we saw internal medicine, pediatric, and gynecologic patients. It was interesting to observe the diagnostic approaches used there. It appeared that doctors relied heavily on historical information and physical examination and ordered fewer diagnostic tests. It is unfortunate that often in American hospitals expensive diagnostic tests seem to be weighted with more importance than a thorough history and physical exam and a doctor's own clinical intuitiveness.

In our second and third weeks we participated in the rural program of San Juan Sacatapaquez, which personally was my favorite segment of the rotation. It was most satisfying to see firsthand and participate in the efforts the Marroquin University is making to deliver health care to its country's people — in our case, the villagers of Aldea Suacite. Living and working among the people of Suacite, we became assimilated in to their way of life. With this integration of health-care workers and native inhabitants, true progress can be made in public health and preventative medicine.

Juan Guzman and Marianna Rodriguez, the two sixth-year medical students from the University, assisted us in every way to make our transition into rural Guatemalan life as easy as possible. The four of us became close professional colleagues as well as personal friends through this experience.

Some of the people I saw and treated will be indelibly imprinted in my memory. There was the time Marianna and I got called to assist a young woman delivering twins in her hut past Los Guatos. I remember the precious faces of the Indian children who came to the clinic because of superior respiratory infections

and to receive vaccinations. Other interesting cases we saw included pneumonia, tuberculosis, septic arthritis, malaria, typhoid fever, and *Trichuris trichiura* with rectal prolapse.

After leaving Suacite, our final week was spent in Roosevelt Hospital. This proved to be as equally an educational experience. We spent time with Dr. Figueroa, his resident, and students who were all extremely helpful and informative. They as well as various other residents eagerly showed us around the hospital and introduced us to some of the interesting patients. In that short amount of time, we were able to observe and discuss patients with tetanus, amoebic liver abscess, scrofula, Grave's Disease, and Schmitt's syndrome.

As mentioned above, I particularly enjoyed the rural program and the time at Roosevelt Hospital. I might suggest that a student be allowed to spend more time at Roosevelt Hospital with a variety of clinical services because of the vast amount of clinical pathology available. The rural program might benefit from having a basic microscope at the clinic if possible. By all means, I believe students should continue to spend at *least* two weeks in the rural villages.

With free time on weekends we were also able to enjoy some of the native attractions of Guatemala. We visited Lake Atitlan, and as we admired the beautiful volcanoes, we managed to receive a sizable sunburn. One weekend we were able to explore the many churches and convents of the ruins of Antigua — what an enchanting city!

The four of us from Mobile, Alabama each came down to Guatemala with different expectations for the month of Tropical Medicine. I'm sure each one of us went away with different feelings of accomplishment. As for me, I again want to thank you for an unforgettable experience that I will look upon as one of the highlights in my medical education.

Deborah L. Campbell
MS IV

Trip Report — III

Dear Dr. Loreneana,

I would like to take this time to thank you for the opportunity which you and your institute afforded me to visit and work in your beautiful country of Guatemala. It was an experience which I believe that I will always remember.

In commenting on my experiences in Guatemala, I first wish to describe what work I was involved in

during the four weeks and then I will address how I felt about the rotation in general and what suggestions I have to offer concerning future externships such as this one.

The first week was spent at the University Hospital Herrera Llerandi outpatient clinic where I saw pediatric, surgical, obstetrical, as well as general medicine patients. As a medical student I was allowed to ex-

amine and offer suggestions for diagnosis and treatment of these patients. The medical students and residents there were fairly knowledgeable of the English language and served well as translators for communication between myself and the patients.

The second and third weeks of the rotation were spent in the rural village of Suacite where I worked closely with your two medical students — Juan Luis Gurman and Marianna Rodriguez. These two students are to be highly praised for their hospitality, medical knowledge, and mastery of the English language. Working with these two students made the whole rural experience worthwhile.

We saw mostly pediatric and obstetrical patients at the Suacite clinic. I noted that one's clinical skills are constantly being tested and trained in a rural setting such as Suacite since laboratory equipment as well as medicine is very limited there and most treatment must be based on history and clinical signs and symptoms. I have found that in order to sharpen your clinical skills, you must use them, and at Suacite you do just that. The rural portion of the rotation definitely offered more of a challenge to my overall general medical knowledge.

The last week was spent in the Roosevelt Hospital. This was perhaps my favorite part of the whole four weeks since it involved much internal medicine and especially infectious diseases. Among the most interesting cases that were seen were cutaneous TB, tetanus, advanced cutaneous fungal infection, and advanced TB with bronchocutaneous fistula and scrofula — all of which are not commonly seen in the United States.

I would highly suggest that, if at all possible, this rotation be preserved so that more students from my institution may be able to experience what I have for

the past month. It is definitely a learning experience which interested persons should not be denied. Future students should be strongly encouraged to participate in the rural program since this portion of the rotation seems to offer the best learning experience.

Although a basic knowledge of your Spanish language would be helpful, I ask that persons not knowledgeable in Spanish not be discouraged from participating in the program since a majority of your students are able to speak English quite well. This is of course a great compliment to your society.

If persons are more interested in internal medicine, it may be feasible for them to remain at Roosevelt Hospital for two weeks instead of just one. This would require, however, that time be taken away from either the outpatient clinic experience or the rural rotation.

Also, perhaps, the time spent at Roosevelt Hospital could somehow become more organized so that students are able to go with the attending physicians and residents on daily hospital ward visits. Interaction with the medical students and residents at Roosevelt Hospital is also very important and enlightening.

Most of all, I enjoyed the flexibility of the whole program. I was allowed to participate in what interested me the most — this was important and I'm sure that future students would also enjoy that same flexibility. I would like to once again stress that this rotation be preserved at all costs since it is a most enriching experience.

I would like to express my appreciation to you and your faculty again for making me feel at home in Guatemala and for allowing me to experience a part of your culture.

Lisa Kay Wright
MS-IV

Trip Report — IV

This exchange of students between the University of South Alabama and Marroquin University in Guatemala City evolved through an association between the Partners of the Americas. As fourth year students at the University of South Alabama we have the opportunity to take electives, not only within our own country, but also abroad. Having been raised in Latin America and knowing many people in Guatemala, I chose Guatemala because I could enjoy the experience fully and introduce Guatemala to my co-workers who would accompany me on the trip.

On February 7, 1987 we left the United States through New Orleans and proceeded to go to Guate-

mala via Miami. At the Guatemala airport we were met by Lorenzo Figueroa and his family. They have been friends with my family for approximately fifteen years. Since we arrived on a week-end, we had a chance to enjoy some of the sites and we went with the Figueras to Antigua, Guatemala which used to be the ancient capital of Guatemala.

Early Monday morning, February 9, 1987, we met with Dr. Rodolfo Lorenzana, who is the Dean of Students of Marroquin University. He sat down with us and explained what we would be doing for the next four weeks. After a delightful chat with Dr. Lorenzana, he proceeded to take us over to the Esperanza Clinic

where we would meet Dr. Romeo DeLeon. Dr. Romeo DeLeon would be our superior for the next week.

The Esperanza Clinic, or as they know it, Departmental A, is a clinic sponsored by the Hospital Herrera Llerandi, the private hospital in town. This clinic is for people of lower socio-economic levels. Here for a nominal fee of five quetzales patients come and are seen initially by house staff of the Marroquin University in the Hospital of Herrera Llerandi. They are then referred to specialists affiliated with that institution. A variety of patients are seen at this clinic, ranging from pediatrics to obstetrics to general surgery patients. The house staff, who are as well trained as house staff here in the United States initially see the patients and discuss the patients among themselves. Patients are also seen initially by fourth and fifth year medical students, then discussed with house staff and finally checked out to Dr. DeLeon who runs the clinic.

Once it is determined what problem the patient has, these patients are usually referred back to Departmental A and scheduled for a clinic visit with a specialist, i.e., dermatology, ear, nose, throat, etc. Thanks to my fluency in Spanish, the change from the University of South Alabama to the Marroquin University wasn't quite as drastic as for my co-workers. I felt it was just a change of environment, but not a total change. At this clinic both students and house staff were eager to see what we thought of the patients problems. After the patients had been seen during the morning clinic, the students and house staff were anxious to show us around the medical facilities and Guatemala City. Their friendliness is just another example of the warmth of the Latin American people.

During the first week's stay at Departmental "A," we found that medicine in Guatemala is much like medicine in the United States. The patients expressed the same problems and they were treated with the same concern as seen in the United States. Other highlights during the week were touring the Hospital Herrera Llerandi, the largest private hospital in Guatemala City. We also took a tour of the Roosevelt Hospital, which is one of the larger public hospitals. During the end of our first week in Guatemala, we met with Dr. Carlos Andrade. He briefed us on what we would be doing for the next two weeks in the rural areas.

At this time we also had an opportunity to meet the fifth year students that we would be working with in the field. During the briefing session he also went over what goals the rural medical program established. The rural medical program was started three years ago by the Marroquin University. It has focused mainly on public health and preventive medicine. For example, one of the aims of the program is to vaccinate all children under five years of age. At this session, Dr. Andrade went over statistics that showed that the perinatal mortality, perinatal morbidity, and infant mor-

continued on page 29



BRIEF SUMMARY

CONTRAINDICATIONS

There are no known contraindications to the use of sucralfate.

PRECAUTIONS

Duodenal ulcer is a chronic, recurrent disease. While short-term treatment with sucralfate can result in complete healing of the ulcer, a successful course of treatment with sucralfate should not be expected to alter the post-healing frequency or severity of duodenal ulceration.

Drug Interactions: Animal studies have shown that the simultaneous administration of CARAFATE with tetracycline, phenytoin, or cimetidine will result in a statistically significant reduction in the bioavailability of these agents. This interaction appears to be nonsystemic in origin, presumably resulting from these agents being bound by CARAFATE in the gastrointestinal tract. The bioavailability of these agents may be restored simply by separating the administration of these agents from that of CARAFATE by two hours. The clinical significance of these animal studies is yet to be defined.

Carcinogenesis, Mutagenesis, Impairment of Fertility: No evidence of drug-related tumorigenicity was found in chronic oral toxicity studies of 24 months' duration conducted in mice and rats at doses up to 1 gm/kg (12 times the human dose). A reproduction study in rats at doses up to 38 times the human dose did not reveal any indication of fertility impairment. Mutagenicity studies have not been conducted.

Pregnancy: Pregnancy Category B. Teratogenicity studies have been performed in mice, rats, and rabbits at doses up to 50 times the human dose and have revealed no evidence of harm to the fetus due to sucralfate. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when sucralfate is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Adverse reactions to sucralfate in clinical trials were minor and only rarely led to discontinuation of the drug. In studies involving over 2,500 patients, adverse effects were reported in 121 (4.7%). Constipation was the most frequent complaint (2.2%). Other adverse effects, reported in no more than one of every 350 patients, were diarrhea, nausea, gastric discomfort, indigestion, dry mouth, rash, pruritus, back pain, dizziness, sleepiness, and vertigo.

DOSAGE AND ADMINISTRATION

The recommended adult oral dosage for duodenal ulcer is 1 gm four times a day on an empty stomach.

Antacids may be prescribed as needed for relief of pain but should not be taken within one-half hour before or after sucralfate.

While healing with sucralfate may occur during the first week or two, treatment should be continued for 4 to 8 weeks unless healing has been demonstrated by x-ray or endoscopic examination.

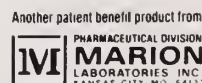
HOW SUPPLIED

CARAFATE (sucralfate) 1-gm pink tablets are supplied in bottles of 100 and in Unit Dose Identification Paks of 100. The tablets are embossed with MARION/1712.

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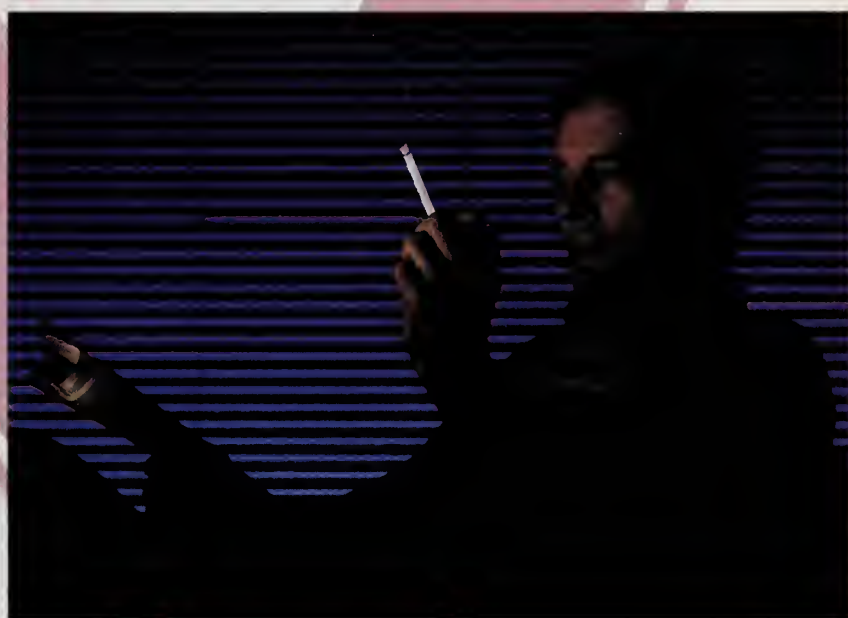
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*Significantly greater than cimetidine smoker group ($P < .05$).

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Only conjugated estrogens tablets have established efficacy in both osteoporosis¹ and vasomotor symptoms* at 0.625 mg/day. No other estrogen, oral or transdermal, has established clinical evidence or minimum effective dose in both indications.

No estrogen proven safer

PREMARIN is the most extensively tested estrogen, with an unsurpassed record of long-term safety.

And clinical evidence shows a significantly reduced risk of endometrial hyperplasia when cycled with a progestin.²

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(conjugated estrogens tablets)

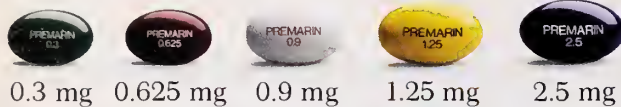
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*PREMARIN is indicated for moderate-to-severe vasomotor symptoms.

Please see following page for brief summary
of prescribing information.

For moderate-to-severe
vasomotor symptoms and
for osteoporosis

PREMARIN® (conjugated estrogens tablets)



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BRIEF SUMMARY (FOR FULL PRESCRIBING INFORMATION AND PATIENT INFORMATION, SEE PACKAGE CIRCULARS.)

PREMARIN® Brand of conjugated estrogens tablets, USP

PREMARIN® Brand of conjugated estrogens Vaginal Cream, in a nonliquefying base

1 ESTROGENS HAVE BEEN REPORTED TO INCREASE THE RISK OF ENDOMETRIAL CARCINOMA

Three independent, case-controlled studies have reported an increased risk of endometrial cancer in postmenopausal women exposed to exogenous estrogens for more than one year. This risk was independent of the other known risk factors for endometrial cancer. These studies are further supported by the finding that incidence rates of endometrial cancer have increased sharply since 1969 in eight different areas of the United States with population-based cancer reporting systems, an increase which may be related to the rapidly expanding use of estrogens during the last decade. The three case-controlled studies reported that the risk of endometrial cancer in estrogen users was about 4.5 to 13.9 times greater than in nonusers. The risk appears to depend on both duration of treatment and on estrogen dose. In view of these findings, when estrogens are used for the treatment of menopausal symptoms, the lowest dose that will control symptoms should be utilized and medication should be discontinued as soon as possible. When prolonged treatment is medically indicated, the patient should be reassessed on at least a semi-annual basis to determine the need for continued therapy. Although the evidence must be considered preliminary, one study suggests that cyclic administration of low doses of estrogen may carry less risk than continuous administration, it therefore appears prudent to utilize such a regimen. Close clinical surveillance of all women taking estrogens is important. In all cases of undiagnosed persistent or recurring abnormal vaginal bleeding, adequate diagnostic measures should be undertaken to rule out malignancy. There is no evidence at present that "natural" estrogens are more or less hazardous than "synthetic" estrogens at equi-estrogenic doses.

2 ESTROGENS SHOULD NOT BE USED DURING PREGNANCY

The use of female sex hormones, both estrogens and progestogens, during early pregnancy may seriously damage the offspring. It has been shown that females exposed in utero to diethylstilbestrol, a nonsteroidal estrogen, have an increased risk of developing, in later life, a form of vaginal or cervical cancer that is ordinarily extremely rare. This risk has been estimated as not greater than 4 per 1,000 exposures. Furthermore, a high percentage of such exposed women (from 30% to 90%) have been found to have vaginal adenosis, epithelial changes of the vagina and cervix. Although these changes are histologically benign, it is not known whether they are precursors of malignancy. Although similar data are not available with the use of other estrogens, it cannot be presumed they would not induce similar changes. Several reports suggest an association between intrauterine exposure to female sex hormones and congenital anomalies, including congenital heart defects and limb-reduction defects. One case-controlled study estimated a 4.7-fold increased risk of limb-reduction defects in infants exposed in utero to sex hormones (oral contraceptives, hormone withdrawal tests for pregnancy, or attempted treatment for threatened abortion). Some of these exposures were very short and involved only a few days of treatment. The data suggest that the risk of limb-reduction defects in exposed fetuses is somewhat less than 1 per 1,000. In the past, female sex hormones have been used during pregnancy in an attempt to treat threatened or habitual abortion. There is considerable evidence that estrogens are ineffective for these indications, and there is no evidence from well-controlled studies that progestogens are effective for these uses. If PREMARIN is used during pregnancy, or if the patient becomes pregnant while taking this drug, she should be apprised of the potential risks to the fetus, and the advisability of pregnancy continuation.

DESCRIPTION: PREMARIN (conjugated estrogens, USP) contains a mixture of estrogens, obtained exclusively from natural sources, blended to represent the average composition of material derived from pregnant mares' urine. It contains estrone, equilin, and 17 α -dihydroequilin, together with smaller amounts of 17 α -estradiol, equilin, and 17 α -dihydroequilin as salts of their sulfate esters. Tablets are available in 0.3 mg, 0.625 mg, 0.9 mg, 1.25 mg, and 2.5 mg strengths of conjugated estrogens. Cream is available as 0.625 mg conjugated estrogens per gram.

INDICATIONS AND USAGE: PREMARIN (conjugated estrogens tablets, USP). Moderate-to-severe vasomotor symptoms associated with the menopause. (There is no evidence that estrogens are effective for nervous symptoms or depression without associated vasomotor symptoms and they should not be used to treat such conditions.) Osteoporosis (abnormally low bone mass). Atrophic vaginitis. Kraurosis vulvae. Female castration.

PREMARIN (conjugated estrogens) Vaginal Cream is indicated in the treatment of atrophic vaginitis and kraurosis vulvae.

PREMARIN HAS NOT BEEN SHOWN TO BE EFFECTIVE FOR ANY PURPOSE DURING PREGNANCY AND ITS USE MAY CAUSE SEVERE HARM TO THE FETUS (SEE BOXED WARNING).

Concomitant Progestin Use: The lowest effective dose appropriate for the specific indication should be utilized. Studies of the addition of a progestin for 7 or more days of a cycle of estrogen administration have reported a lowered incidence of endometrial hyperplasia. Morphological and biochemical studies of the endometrium suggest that 10 to 13 days of progestin are needed to provide maximal maturation of the endometrium and to eliminate any hyperplastic changes. Whether this will provide protection from endometrial carcinoma has not been clearly established. There are possible additional risks which may be associated with the inclusion of progestin in estrogen replacement regimens. (See PRECAUTIONS.) The choice of progestin and dosage may be important; product labeling should be reviewed to minimize possible adverse effects.

CONTRAINDICATIONS: Estrogens should not be used in women (or men) with any of the following conditions: 1. Known or suspected cancer of the breast except in appropriately selected patients being treated for metastatic disease. 2. Known or suspected estrogen-dependent neoplasia. 3. Known or suspected pregnancy (see Boxed Warning). 4. Undiagnosed abnormal genital bleeding. 5. Active thrombophlebitis or thromboembolic disorders. 6. A past history of thrombophlebitis, thrombosis, or thromboembolic disorders associated with previous estrogen use (except when used in treatment of breast or prostatic malignancy).

WARNINGS: Estrogens have been reported to increase the risk of endometrial carcinoma (see Boxed Warning). However, a recent large, case-controlled study indicated no increase in risk of breast cancer in postmenopausal women. A recent study has reported a 2- to 3-fold increase in the risk of surgically confirmed gallbladder disease in women receiving postmenopausal estrogens.

Adverse effects of oral contraceptives may be expected at the larger doses of estrogen used to treat prostatic or breast cancer or postpartum breast engorgement; it has been shown that there is an increased risk of thrombosis in men receiving estrogens for prostatic cancer and women for postpartum breast engorgement. Users of oral contraceptives have an increased risk of diseases, such as thrombophlebitis, pulmonary embolism, stroke, and myocardial infarction. Cases of retinal thrombosis, mesenteric thrombosis, and optic neuritis have been reported in oral contraceptive users. An increased risk of postsurgery thromboembolic complications has also been reported in users of oral contraceptives. If feasible, estrogen should be discontinued at least 4 weeks before surgery of the type associated with an increased risk of thromboembolism, or during periods of prolonged immobilization. Estrogens should not be used in persons with active thrombophlebitis, thromboembolic disorders, or in persons with a history of such disorders in association with estrogen use. They should be used with caution in patients with cerebral vascular or coronary artery disease. Large doses (5 mg conjugated estrogens per day), comparable to those used to treat cancer of the prostate and breast, have been shown to increase the risk of nonfatal myocardial infarction, pulmonary embolism, and thrombophlebitis. When doses of this size are used, any of the thromboembolic and thrombotic adverse effects should be considered a clear risk.

For atrophic vaginitis

PREMARIN® (conjugated estrogens)

Vaginal
Cream

0.625 mg/g



Benign hepatic adenomas should be considered in estrogen users having abdominal pain and tenderness, abdominal mass, or hypovolemic shock. Hepatocellular carcinoma has been reported in women taking estrogen-containing oral contraceptives. Increased blood pressure may occur with use of estrogens in the menopause and blood pressure should be monitored with estrogen use. A worsening of glucose tolerance has been observed in patients on estrogen-containing oral contraceptives. For this reason, diabetic patients should be carefully observed. Estrogens may lead to severe hypercalcemia in patients with breast cancer and bone metastases.

PRECAUTIONS: Physical examination and a complete medical and family history should be taken prior to the initiation of any estrogen therapy with special reference to blood pressure, breasts, abdomen, and pelvic organs, and should include a Papanicolaou smear. As a general rule, estrogen should not be prescribed for longer than one year without another physical examination being performed. Conditions influenced by fluid retention, such as asthma, epilepsy, migraine, and cardiac or renal dysfunction, require careful observation. Certain patients may develop manifestations of excessive estrogenic stimulation, such as abnormal or excessive uterine bleeding, mastodynia, etc. Prolonged administration of unopposed estrogen therapy has been reported to increase the risk of endometrial hyperplasia in some patients. Oral contraceptives appear to be associated with an increased incidence of mental depression. Patients with a history of depression should be carefully observed. Pre-existing uterine leiomyomata may increase in size during estrogen use. The pathologist should be advised of estrogen therapy when relevant specimens are submitted. If jaundice develops in any patient receiving estrogen, the medication should be discontinued while the cause is investigated. Estrogens should be used with care in patients with impaired liver function, renal insufficiency, metabolic bone diseases associated with hypercalcemia, or in young patients in whom bone growth is not yet complete. If concomitant progestin therapy is used, potential risks may include adverse effects on carbohydrate and lipid metabolism.

The following changes may be expected with larger doses of estrogen:

- Increased sulfobromophthalen retention
- Increased prothrombin and factors VII, VIII, IX, and X, decreased antithrombin 3, increased norepinephrine-induced platelet aggregability
- Increased thyroid binding globulin (TBG) leading to increased circulating total thyroid hormone, as measured by PBI, T_4 by column, or T_4 by radioimmunoassay. Free T_3 resin uptake is decreased, reflecting the elevated TBG. Free T_4 concentration is unaltered.
- Impaired glucose tolerance
- Decreased pregnandiol excretion
- Reduced response to meprobamate test
- Reduced serum folate concentration
- Increased serum triglyceride and phospholipid concentration

As a general principle, the administration of any drug to nursing mothers should be done only when clearly necessary since many drugs are excreted in human milk.

Long-term, continuous administration of natural and synthetic estrogens in certain animal species increases the frequency of carcinomas of the breast, cervix, vagina, and liver. However, in a recent, large case-controlled study of postmenopausal women there was no increase in risk of breast cancer with use of conjugated estrogens.

ADVERSE REACTIONS: The following have been reported with estrogenic therapy, including oral contraceptives: breakthrough bleeding, spotting, change in menstrual flow, dysmenorrhea, premenstrual-like syndrome, amenorrhea during and after treatment, increase in size of uterine fibromyomata, vaginal candidiasis, change in cervical erosion and in degree of cervical secretion, cystitis-like syndrome, tenderness, enlargement, secretion (of breasts), nausea, vomiting, abdominal cramps, bloating, cholestatic jaundice, chloasma or melasma which may persist when drug is discontinued, erythema multiforme, erythema nodosum, hemorrhagic eruption, loss of scalp hair, hirsutism, steepening of corneal curvature, intolerance to contact lenses, headache, migraine, dizziness, mental depression, chorea, increase or decrease in weight, reduced carbohydrate tolerance, aggravation of porphyria, edema, changes in libido.

ACUTE OVERDOSAGE: May cause nausea, and withdrawal bleeding may occur in females.

DOSEAGE AND ADMINISTRATION:

PREMARIN® Brand of conjugated estrogens tablets, USP

1. Given cyclically for short-term use only. For treatment of moderate-to-severe vasomotor symptoms, atrophic vaginitis, or kraurosis vulvae associated with the menopause (0.3 mg to 1.25 mg or more daily). The lowest dose that will control symptoms should be chosen and medication should be discontinued as promptly as possible. Administration should be cyclic (eg, three weeks on and one week off). Attempts to discontinue or taper medication should be made at three- to six-month intervals.

2. Given cyclically. Osteoporosis: Female castration. Osteoporosis—0.625 mg daily. Administration should be cyclic (eg, three weeks on and one week off). Female castration—1.25 mg daily, cyclically. Adjust upward or downward according to response of the patient. For maintenance, adjust dosage to lowest level that will provide effective control.

Patients with an intact uterus should be monitored for signs of endometrial cancer and appropriate measures taken to rule out malignancy in the event of persistent or recurring abnormal vaginal bleeding.

PREMARIN® Brand of conjugated estrogens Vaginal Cream

Given cyclically for short-term use only. For treatment of atrophic vaginitis or kraurosis vulvae.

The lowest dose that will control symptoms should be chosen and medication should be discontinued as promptly as possible.

Administration should be cyclic (eg, three weeks on and one week off).

Attempts to discontinue or taper medication should be made at three- to six-month intervals.

Usual dosage range: 2 g to 4 g daily, intravaginally, depending on the severity of the condition.

Treated patients with an intact uterus should be monitored closely for signs of endometrial cancer and appropriate diagnostic measures should be taken to rule out malignancy in the event of persistent or recurring abnormal vaginal bleeding.

References:

- Lindsay R, Hart OM, Clark OM. The minimum effective dose of estrogen for prevention of postmenopausal bone loss. *Obstet Gynecol* 1984;63:759-763.
- Studd JWW, Thom MH, Paterson MEL, et al: The prevention and treatment of endometrial pathology in postmenopausal women receiving exogenous estrogens. In Pasetto N, Paoletti R, Ambrosi JL (eds). *The Menopause and Postmenopause*. Lancaster, England, MTP Press Ltd, 1980, chap 13.

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Trip Report — IV

continued from page 24

tality had been dramatically reduced over the past three years. After the meeting we all agreed to meet back at the University on Monday morning at 6:30, so that we could be on the road to San Juan Sacatepequez. We spent that week-end touring at the lake, which is one of the largest in Guatemala, located about 150 kilometers west of Guatemala City. We stayed here with Lorenzo Figueroa and his family at their house on the lake.

When Monday morning arrived, we were all eager to reach San Juan Sacatepequez. San Juan is a municipality surrounded by ten or fifteen villages of which six or seven would have medical students permanently installed for the next six months. After reaching San Juan, we went further on to a town named Pachali and met with Dr. Jorge Palacios, another physician associated with the rural medicine program. He began to brief us, along with Dr. Andrade, on what our assignments would be for the next two weeks. At this time he introduced us to an organized system of paperwork which was aimed to make things easier when treating patients in this rural area.

One of these forms was a prenatal care form which included a prenatal history of the mother, past medical history, current nutritional status, etc. This form was very similar to the form used at South Alabama. Another form we were instructed on how to use was the "fichafamiliar." This translates to family chart. On this chart was the number of the house the family lived in, the year the family census was taken, along with names of everyone in the family. Every three months a new census was taken, at which time the number within the family is determined, as were children under five years of age, pregnant women and women in child-bearing years. On the front of this chart it was noted whether the house had a latrine, if they used public water or had to go to the river for water, if they had a well, etc. On opening up the family chart there was a detailed history of the children under five years of age relating to nutritional status and dates of vaccines. On the bottom of the page there was also a detailed past medical history, over the past year.

In this area, the native townspeople have not totally accepted modern medicine. This is most evident at the time a woman delivers a child. Over 95% of the children born in the village of Cerroalto, the village in which we were staying, were delivered by midwives. The remaining 5% of the children were either born alone or with the assistance of a doctor. Most of the midwives in Cerroalto are imperial midwives, that is they have had no formal training. However, now most of the midwives are working jointly with the medical staff at the public health post in Cerroalto. A good relationship between doctors and midwives is essential

in continuing the care to the patient.

Many patients are reluctant to come to the doctor for problems with their pregnancy unless their midwife is in agreement with this. Periodically the medical staff at the health post and the midwives all meet and discuss any problems or differences. At these meetings the midwives are also taught on how to handle minor emergencies. Many of the midwives recognize their limitations and when a problem arises they contact the physician.

Two sixth year medical students from the Marroquin University are assigned to each health post. Rusty, my partner from the states, and I accompanied Juan Carlos and Patty for the first two weeks. These medical students, as a part of their graduation requirement, are assigned to these health posts for six months at a time. During the six months they live at the health post, which is equipped with a room, a kitchen, and a bathroom. The students are allowed to go back to Guatemala City on the weekends which is only an hours' drive away. They must return every Monday morning to man the post.

During the week, the clinic would be open from eight to five. During this time we would see all patients that came into the clinic. Most of the consultations were pediatric in nature. One fact that impressed me greatly was that malnutrition was not that evident in this area. As a rule most of the pediatric visits were just like visits at clinics in the United States, for common things such as otitis media, common colds, diarrhea, etc. As a matter of fact most of the clinic consultations were quite similar to what we see in the United States, although we did see cases of typhoid fever, malaria and extra-pulmonary tuberculosis. While at this health post the students also visited, on a weekly basis, smaller villages that surrounded Cerroalto. These villages are from one to five kilometers away and can be reached only by foot.

All in all I was very impressed by the quality of health care that is delivered in these village health posts. I thought that it was very well organized and the staff was very capable. There is only one very real problem in this area, and that is the lack of medication. Many times the diagnosis is made and the treatment is decided upon but there is no medicine. I think this rural area health service has had a great impact on health care in the area, and without it the area would greatly suffer.

The final week was spent in Guatemala City. Dr. Lorenzana gave us the opportunity to choose what we would be doing for the next week. I chose to stay at Departmental "A" where we had spent the first week. What impressed me about this clinic was the amount of time spent with each patient. Also there were numerous cases of great interest concentrated into one afternoon. The last week was much like the first week, with the exception that I concentrated more on sub-

specialties, i.e. dermatology and rheumatology, than the general medicine in-take clinic.

I feel the trip to Guatemala was extremely successful in that the Guatemalans learned from us and we learned from the Guatemala people. I think that the original objectives of the trip were completely fulfilled. One thing I do regret, however, is that we could not stay longer. Just as we were making new friends we had to leave Guatemala. I plan to stay in contact with both students and house staff.

One of the goals mentioned to me most frequently by the Guatemalan physicians, namely Dr. Carlos Andrade, was to totally computerize all of the family charts that I mentioned before, and with the aid of a personal computer have all necessary data easily ac-

cessible. He asked me to inquire if there was someone willing to donate a personal computer and peripherals as the cost of these are prohibitive in Guatemala City.

In closing, I would like to thank the Partners of the Americas for their travel arrangements, Dr. Samuel Eichold for making this trip possible and Dr. Rodolfo Lorenzana for all of his attentions while we were at the University. Also at this time I would like to convey special thanks to Lorenzo Figueroa and his family without which this trip would not have been the same. In the future, I recommend this course to students that have a moderate or better knowledge of Spanish. □

Niki Oquist
MS-IV

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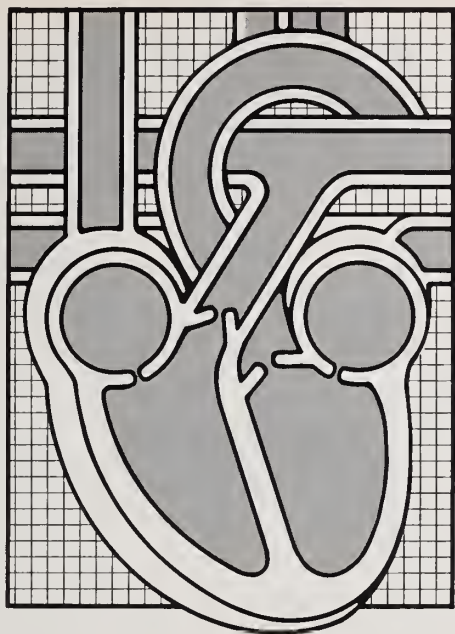
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The Liver and Pregnancy

W. Roger Carlisle, M.D., F.A.C.P.*

Liver disease in pregnancy can be divided into two major categories. Category (I) is liver disease which is primary and secondary to pregnancy. Category (II) is liver disease associated with pregnancy and affected by pregnancy.

The primary liver diseases of pregnancy are: hyperemesis gravidarum, benign intrahepatic cholestasis, preeclampsia, fatty liver of pregnancy, and acute hepatic hemorrhage. These five disease entities are all peculiar to pregnancy and seen only in pregnancy. All of these conditions are associated with abnormal liver tests.

The five primary liver diseases of pregnancy all show some elevation of the bilirubin. The bilirubin in preeclampsia is often elevated in the 10-12 range and is generally unconjugated. The bilirubin in fatty liver of pregnancy is often elevated in the 8-12 range. The bilirubin is generally less than 5 (5) in benign intrahepatic cholestasis, hyperemesis gravidarum, and in acute hepatic hemorrhage (see Table 1).

The most common disease in pregnancy is actually hepatitis. Hepatitis makes up approximately 40% of all liver diseases associated with pregnancy. Classically, the SGOT is elevated at 10 times normal and the bilirubin is greater than 3.5. Fulminant hepatitis is

often difficult to differentiate from fatty liver of pregnancy. The liver in normal pregnancy shows some liver test abnormalities. There is elevation of the fibrinogen, ceruloplasmin, clotting factors, alkaline phosphatase, and blood volume. These liver tests and laboratory abnormalities are seen in normal pregnancy.

The gamma GTP increases two times normal. The SGOT and SGPT increased approximately 5%. There is a normal increase in cholesterol and triglycerides.

A marked fall in the alkaline phosphatase often correlates with fetal death. The abnormal increase in the alkaline phosphatase is due to a fraction from the placenta and a small fraction from bone.

Hepatitis A is the most common disease of the liver seen in pregnancy. Hepatitis A is not tetragenic. There is an increased risk of premature labor and birth. The best test for detecting hepatitis A is the anti-A IGM antibody. Hepatitis A is a fecal water-borne disease with a seven week incubation. Reports of clinical relapse and repeat shedding of the virus have recently been reported in the *Annals of Internal Medicine* by Dr. Tanno and Cohen.¹ The best therapy for hepatitis A is good, careful nutrition and gamma globulin to be given to expose family members.

Hepatitis B has now been divided into acute and chronic disease. The chronic disease can be active-chronic hepatitis or can be present in an integrated

* Birmingham, Alabama.

TABLE 1
Liver Diseases of Pregnancy

Hyper Emesis Gravidarum	Benign (recurrent) Intrahepatic Cholestasis	Pre-eclampsia
SGOT 3 × ↑ BILI 3.5 I	SGOT 5 × BILI < 5.0 II	LDH ↑ SGOT 5 × (uncon) BILI 10 III
FLP	Hepatitis	Hepatic Hemorrhage
SGOT 10 × Bili ~ 10.0 III	SGOT 10 × BILI 3.5 All Trimesters	↓ PCV

form where small pieces of genetic material are incorporated into the liver cell. Hepatitis B can be spread only through blood contamination, semen, saliva, or vaginal secretions. Hepatitis B is a DNA virus. The viral coat is produced in the cytoplasm of the liver cell. The virus is usually spread to the fetus at the time of delivery. There have been cases of viral spread in utero prior to delivery documented. There is an increased incidence of prematurity with hepatitis B. In general, the mother does well. Prematurity only occurs if the mother is infected in the third trimester. It is recommended that all mothers be screened with hepatitis B surface antigen with the hepatitis B surface antigen blood test.

It is also recommended that all mothers with hepatitis B in the third trimester will require therapy for their infants. The infants of hepatitis B mothers should receive HepatoVax as well as the hyperimmune globulin at 1, 3, and 6 months.

Non-A, non-B hepatitis is poorly understood and studied since there are no good viral markers for this disease. Water-borne non-A hepatitis in New Deli and in Pakistan has been associated with a 40% incidence of maternal mortality during pregnancy. This hepatitis is generally diagnosed by ruling out CMV, Epstein-Barr, and other common hepatitic viruses. Therapy with pooled immune globulin may be helpful for exposed family members and the fetus. The differential diagnosis of jaundice in pregnancy includes: Gilbert syndrome, fatty liver of pregnancy, benign cholestasis, toxemia, intercurrent or unrelated gallstone or liver disease, hepatitis, and bile duct obstruction. Hepatitis is the most common cause of jaundice and accounts for 41%, toxemia of pregnancy accounts for 21%, gallstone and bile duct obstruction account for less than 5% of cases with jaundice. Unusual causes of jaundice in pregnancy include the HELLP syndrome, hydatidiform mole, megaloblastic anemia of preg-

nancy, and sepsis.² The concurrent diseases which may be exacerbated by pregnancy include hepatitis, drug cholestasis, biliary obstruction, sclerosing cholangitis, primary biliary cirrhosis, Wilson's disease, hemolysis, congenital hyperbilirubinemia, and any other underlying liver disease.²

The most commonly seen liver test abnormality in pregnant patients is benign intrahepatic cholestasis of pregnancy. This disease is generally felt to be benign for the mother. There is a genetic predisposition to this condition that commonly affects women from Chile, Sweden, and the Andes. Benign cholestasis of pregnancy always develops in the third trimester and is always associated with some abnormality of the liver tests. Pruritus is the first symptom. This disease tends to be recurrent with every pregnancy and is often seen with oral contraceptives.³

Patients with intrahepatic cholestasis usually have elevation of the SGOT and SGPT in 75% of cases. The SGOT and SGPT are generally less than 500. The bilirubin is increased in 20%. Increased lipids, cholesterol, and triglycerides are also common. The liver biopsy shows only centrilobular cholestasis. Although the prognosis for the mother is very good, the prognosis for the infant is not benign. There is a 10% increase in the incidence of fetal death, low birth weight, and perinatal complications. There is 50% incidence of C-Section and these infants require very close monitoring.³

The most ominous liver disease of pregnancy is the fatty liver disease of pregnancy. This disease carries an 85% mortality. Recent publications and case reports have indicated the lesser mortality in the 20-30% range. The mortality has been reduced by careful attention to bleeding dyscrasias, and aggressive treatment of sepsis. This disease is very ominous because of the vague symptoms of anorexia, nausea, and malaise. Fatty liver of pregnancy always occurs in the third trimester and 50% of these cases are associated with fetal death. The biopsy shows microvesicular fat in the hepatocyte. Fatty liver disease of pregnancy is not felt to be recurrent in future pregnancies.⁴⁻⁵

The laboratory and FLP shows a bilirubin of less than 10, SGOT in the 500-1000 range. Patients often have decreased fibrinogen and anti thrombin III levels. The patients have positive fibrin split products, leukocytosis, thrombocytopenia, giant platelets, and no schistocytes. The patients have hypoglycemia and almost always have an elevated bilirubin. Patients with fatty liver of pregnancy may develop DIC. The DIC may be persistent due to depletion of clotting factors, protein C, and antiprothrombin III. Antiprothrombin III and protein C are synthesized by the liver. Protein C is a potent inhibitor of activated factor 5 and 8 as well as an activator of fibrinolysis. Both antiprothrombin III and protein C are consumed in the progress of intravascular coagulation. Patients with fatty liver of

pregnancy have no ability to regenerate antithrombin III.⁶

The use of Aminocaproic acid is unwise. These patients often require cryoprecipitate to correct the hypofibrinogenemia and fresh frozen plasma to correct the levels of antithrombin III. Many dose Heparin can also be used every 12 hours to stabilize antithrombin III levels.⁶ The pathogenesis of fatty liver of pregnancy is still unknown. There may be hormonal factors and drug factors which complicate this issue. Management of patients with fatty liver of pregnancy requires attentions to the complications of bleeding and sepsis. Patients often require Vitamin K, fresh frozen plasma, and platelets. The use of clotting factor concentrates should be avoided. It is generally recommended that the patient have rapid delivery of the fetus with induced delivery or C-Section.⁶

The other considerations for evaluation in a patient with apparent fatty liver would include fulminant hepatitis, toxemia of pregnancy, hepatic rupture, Budd-Chiari Syndrome, and severe underlying liver disease. The second most common liver disease of pregnancy is preeclampsia. Preeclampsia again has a subtle onset with nausea, vomiting, and abdominal pain. Patients will have eclamptic symptoms of hypertension, edema, and proteinuria. Preeclampsia is often associated with DIC, tender hepatomegaly, hepatic rupture, and coma. The liver test abnormalities tend to be milder. The SGOT ranges from 300 to 500. The bilirubin generally ranges from 2-5. If the patient does have right upper quadrant pain, an emergency ultrasound should be done to rule out subcapsular hematoma and impending hepatic rupture.⁷⁻⁸ Eclampsia and preeclampsia of pregnancy are also associated with the HELLP syndrome (Table II). The HELLP syndrome stands for "Hemolysis, Elevated Liver Tests and Proteinuria." These patients will be found to have fibrin deposition in the sinusoids on liver biopsy. There is often hemorrhagic necrosis of the liver with hematomas and coalescence of the hematomas. The patients will be found to have schistocytes on their peripheral smear which are not seen in fatty liver. There is often DIC, hemolysis, and elevation of the LDH. The elevated LDH enzyme is a hallmark and a key indicator that the patient may have preeclampsia rather than hepatitis.⁷⁻⁸ Recent study by Rolfes and Ishak shows a 70% mortality rate in patients with liver disease and a 33% mortality in pa-

TABLE 2
HELLP Syndrome

A. (H) — hemolysis
(EL) — elevated liver enzymes (SGOT)
(LP) — low platelet count
B. Seen in toxemia with hypertension, proteinuria, cerebral edema, pulmonary edema
C. Abnormal peripheral smear: bun cells or schistocytes
D. Therapy with antihypertensives (Hydralazine)
FFP
C-Section
Antibiotics
Hypoglycemia

tients with liver symptoms.⁸ Therapy for the preeclampsia includes antihypertensives, Hydralazine, fresh frozen plasma, C-Section, antibiotics, and treatment of possible hypoglycemia.⁷⁻⁸

In summary, viral prophylaxis is very important in liver disease and pregnancy. All pregnant females should be screened for hepatitis B with a hepatitis B surface antigen. Hepatitis B in the second and third trimester will show vertical transmission. All infants' mothers with hepatitis B in the third trimester should receive both hepatitis immune globulin. The dose is 0.6 mgs. per kg. at the time of delivery. The infants should also receive Hepatovax at a dose of 10 mg. IM at 1 week, 1 month, and 6 months.

Hepatic dysfunction in pregnancy is important because it often reflects advanced life-threatening disease. □

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Reporting of Congenital Malformations on Alabama Birth Certificates

Ruth Whisonant
Betty Shine
Ray Graham
Dale Quinney*

Introduction

On January 8, 1986 a proposal was made by the Division of Statistical Analysis of the Bureau of Vital Statistics to conduct a sample study of the comparison between the congenital anomalies listed on the birth certificate filed in the Bureau of Vital Statistics and the congenital anomalies listed on the corresponding hospital medical record at the time of birth (attachment A). On February 19, 1986 the Alabama State Committee of Public Health gave approval to conduct this study (attachment B). Approval was also obtained from the Alabama Hospital Association on May 29, 1986 (attachment C). Letters were written to the administrator of each hospital to be visited to obtain approval to review the medical records of the infants named on the birth certificates included in the sample (sample letter attachment D).

The stated purpose of the study was to determine the degree of completeness of reporting congenital anomalies on the birth record. The theory had been made that all anomalies are not reported on the birth record and the study was designed to prove or disprove this theory.

Methodology

From the 1985 birth file, a computer listing was made of all certificate numbers that showed a congenital anomaly on the birth record. These numbers along with the infant's name, mother's name, race, sex, hospital of birth, county of birth, county of residence, attendant and International Classification of Diseases, adapted for use in the United States (ICDA) code for the anomaly (or anomalies) was entered into a personal computer file. These were printed out on individual forms to be used by the field teams to take to the hospital of birth to see if all the anomalies listed on the hospital record had been transcribed on to the birth certificate.

A random sample of all birth certificates not listing congenital anomalies was obtained from the computer. Information from these records was also entered into the computer file and printed out on individual forms to be used by the field teams to check the hospital record of the infant to see if any congenital anomalies had been omitted from the birth certificate.

All records to be checked from both sources were filed in a county folder by hospital of occurrence. All hospitals agreed to participate in the study with the exception of three hospitals which required that we furnish a legal opinion as to the right of the Alabama

* Division of Statistical Analysis Services, Forest E. Ludden, Ed.D., M.P.H., State Registrar and Director, Bureau of Vital Statistics, Alabama Department of Public Health, State Office Building, Montgomery, Alabama 36130.

Department of Public Health to review their records (attachment E). Two other hospitals were reluctant to allow the reviewing of their records but did so after assurance was given that confidentiality would be maintained. The field teams began reviewing hospital records on July 14, 1986 in Montgomery County. All information concerning congenital anomalies contained in the hospital record was copied to the individual infant's questionnaire used by the field team. The forms were then brought back to the Bureau of Vital Statistics and a trained, experienced coder reviewed and coded each anomaly using the accepted ICDA. The computer files were then updated to include these codes.

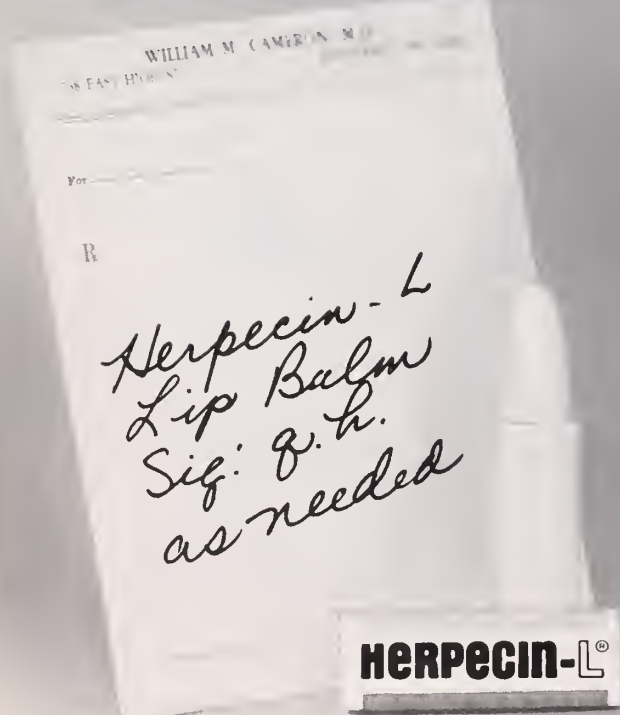
Field visits were delayed during the fall of 1986 due to the remodeling and physical moving of the offices of the Bureau of Vital Statistics. During the course of this survey, it was found that three records from the group that had congenital anomalies listed on the birth certificate would have to be eliminated from the study. One birth had occurred in the Fairview Medical Center in Montgomery which had ceased to function during the year and the record could not be found. The second birth had occurred at home and the family could not be visited to obtain information. The third birth occurred in a hospital that could not locate the record after two visits and due to limited time and expense the record was deleted from the study.

Discussion

There were 58,628 births occurring in Alabama during 1985. Of that number 439 or 0.7 percent were recorded with one or more congenital anomalies listed on the birth certificate. Since three of these records were eliminated from the study, the remainder of 436 birth certificates were compared to the respective hospital record of the hospital in which the birth occurred. There was a total of 503 congenital anomalies listed on the 436 birth certificates. By comparison, after checking the hospital records for the 436 infants it was determined that an additional 169 congenital anomaly codes should have been listed on the birth records making a total of 672 congenital anomalies for these infants. This means that 25.1 percent of the congenital anomalies occurring to these 436 infants were omitted from their birth certificates. The congenital anomalies most often omitted from these certificates were ICDA code number 744.2 or Other Specified Anomalies of the Ear and ICDA code 754.7 or Other Deformities of Feet, Including Asymmetric Clubfoot NOS, Congenital Deformity of Foot NOS, etc. Others omitted more than eight times included ICDA code 746.9 or Unspecified Anomalies of Heart and 757.3 or Other Specified Anomalies of Skin Including Accessory Skin Tags, Birthmarks, etc.

There were 12 ICDA codes for congenital anomalies
continued on page 40

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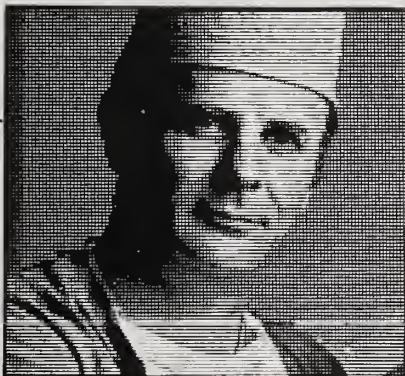
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Reporting of Congenital Malformations

continued from page 38

listed on the birth certificates that were changed when it was discovered that the hospital record had a different terminology for the anomaly than the terminology used on the birth certificate and the different wording of the hospital record helped to clarify the coding process.

There were 554 random sample records of birth certificates that did not list any anomalies on the birth record. These certificates were also checked against the corresponding hospital records. It was found that 51 of these birth certificates should have had 59 congenital anomalies listed. This means that 9.2 percent of the 554 sample birth records should have listed a malformation. The most frequent congenital anomaly omitted from these records was ICDA code 757.3 or Other Specified Anomalies of Skin. This included birthmarks, accessory skin tags, congenital scar, congenital ectodermal, etc. The second most frequent omission from these records was ICDA code 754.3 or Congenital Dislocation of Hip. The third most frequent omission was ICDA code 752.5 or Undescended Testicle.

Combining the two groups there was 990 records in the sample. The birth certificates listed a total of 503 congenital anomalies. The corresponding hospital records showed a total of 731 congenital anomalies for these same infants. This confirms our theory that all anomalies are not reported on the birth certificates. In this sample only 68.8 percent of the recorded anomalies

were reported on the birth certificates. The most serious, obvious anomalies were reported more frequently than the less obscure ones. Anencephalus, spina bifida, hydrocephalus and anomalies of the limbs were reported at least 80 percent of the time while anomalies of the eye, ear, face, neck, skin, hair, nails, etc. were reported on the birth certificate less than 50 percent of the time.

Conclusion

In general the hospital medical record personnel were very helpful and cooperative. This was especially true in the larger hospitals. Some of the smaller hospitals were more reluctant to allow us to review the hospital record and seemed more concerned about the legality of the review and the possibility of lawsuits.

Each hospital had a different kind of form upon which the anomalies of the infants were recorded. Many were difficult to read as they were recorded in the handwriting of the attendant. These terms were later transcribed to a birth record and many of the congenital anomaly terms were omitted or misinterpreted. One theory is that many hospital record personnel have possible misunderstandings as to what constitutes a congenital anomaly.

Another possible reason for the omission of many congenital anomalies from the birth record is the lack of recording space on the present birth certificate when an infant is the victim of more than one anomaly. The newly proposed Alabama birth record, following the guidelines of the United States standard certificate, will have a check-off section to indicate as many as

TABLE I
Comparison of the Birth Certificate and Hospital Record for Completeness of Reporting Specific Malformations
Alabama, 1985

<i>Anomaly</i>	<i>ICDA Code</i>	<i>Hospital Record</i>	<i>Birth Certificate</i>	<i>Percent Reported on Birth Certificate</i>
Anencephalus	740	10	8	80.0
Spina Bifida	741	33	28	84.8
Nervous System	742	46	36	78.3
Eye	743	26	9	34.6
Ear, Face and Neck	744	18	7	38.9
Heart	746	23	12	52.2
Circulatory System	747	11	7	63.6
Respiratory System	748	10	7	70.0
Cleft Palate and Cleft Lip	749	53	44	83.0
Upper Alimentary Tract	750	19	13	68.4
Digestive System	751	21	13	61.9
Genital	752	71	49	69.0
Urinary System	753	13	12	92.3
Musculoskeletal Deformities	754	84	50	59.5
Limb	755	134	119	88.8
Other Musculoskeletal Anomalies	756	34	15	44.1
Skin, Hair and Nails	757	60	27	45.0
Chromosomal Abnormalities	758	29	20	69.0
Other and Unspecified Congenital Anomalies	759	36	27	75.0
TOTAL		731	503	68.8

22 congenital anomalies for each child. This will help to give a clearer picture of the congenital anomalies that occur to the infants of Alabama. Hopefully, this new birth certificate will go into effect in 1988.

In addition to the new proposed birth certificate which will hopefully improve the reporting of congenital anomalies on the birth record, an education program among hospital medical records personnel concerning the kinds of malformations would be desired. While the attendant (physician) usually lists all anomalies on the medical chart, in the transferring of these terms to the birth certificate some are omitted. This may be due to lack of knowledge of which term is a codable congenital anomaly.

As stated in the original proposal, our objective was to determine whether all anomalies on the hospital medical record chart had been recorded on the birth certificate. We have determined that they were not so recorded. As also stated in the proposal, information gathered on the field trips can be used late in other congenital anomaly studies. ■

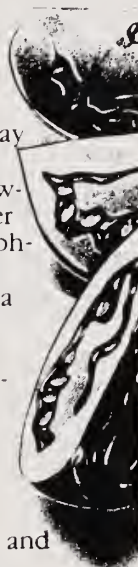
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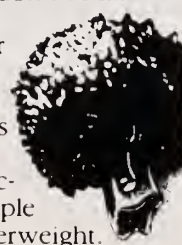
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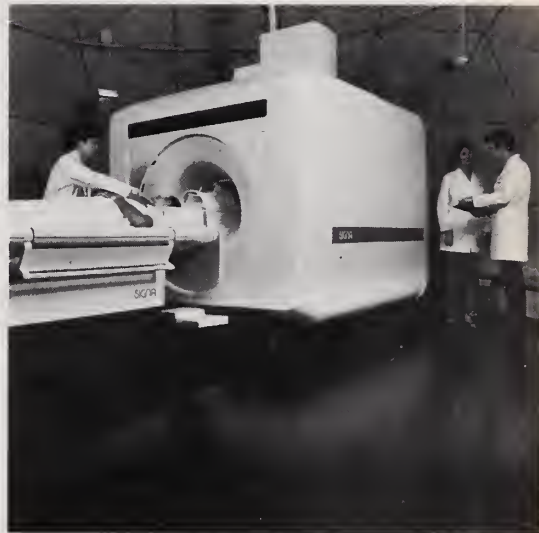
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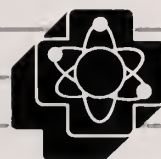


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Inderal LA should not be considered a simple mg-for-mg substitute for conventional propranolol and the blood levels achieved do not match (are lower than) those of two to four times daily dosing with the same dose. When changing to Inderal LA from conventional propranolol, a possible need for retitration upwards should be considered especially to maintain effectiveness at the end of the dosing interval. In most clinical settings, however, such as hypertension or angina where there is little correlation between plasma levels and clinical effect, Inderal LA has been therapeutically equivalent to the same mg dose of conventional Inderal, as assessed by 24-hour effects on blood pressure and on 24-hour exercise responses of heart rate, systolic pressure and rate pressure product. Inderal LA can provide effective beta blockade for a 24-hour period.

INDICATIONS AND USAGE. **Hypertension:** Inderal LA is indicated in the management of hypertension. It may be used alone or used in combination with other antihypertensive agents, particularly a thiazide diuretic. Inderal LA is not indicated in the management of hypertensive emergencies.

Angina Pectoris Due to Coronary Atherosclerosis: Inderal LA is indicated for the long-term management of patients with angina pectoris.

Migraine: Inderal LA is indicated for the prophylaxis of common migraine headache. The efficacy of propranolol in the treatment of a migraine attack that has started has not been established and propranolol is not indicated for such use.

Hypertrophic Subaortic Stenosis: Inderal LA is useful in the management of hypertrophic subaortic stenosis, especially for treatment of exertional or other stress-induced angina, palpitations, and syncope. Inderal LA also improves exercise performance. The effectiveness of propranolol hydrochloride in this disease appears to be due to a reduction of the elevated outflow pressure gradient which is exacerbated by beta-receptor stimulation. Clinical improvement may be temporary.

CONTRAINDICATIONS. Inderal is contraindicated in 1) cardiogenic shock, 2) sinus bradycardia and greater than first-degree block, 3) bronchial asthma, 4) congestive heart failure (see WARNINGS) unless the failure is secondary to a tachyarrhythmia treatable with Inderal.

WARNINGS. **CARDIAC FAILURE.** Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive heart failure, and its inhibition by beta blockade may precipitate more severe failure. Although beta blockers should be avoided in overt congestive heart failure, if necessary, they can be used with close follow-up in patients with a history of failure who are well compensated and are receiving digitalis and diuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitalis on heart muscle.

IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta blockers can, in some cases, lead to cardiac failure. Therefore, at the first sign or symptom of heart failure, the patient should be digitalized and/or treated with diuretics, and the response observed closely, or Inderal should be discontinued (gradually, if possible).

IN PATIENTS WITH ANGINA PECTORIS, there have been reports of exacerbation of angina and, in some cases, myocardial infarction, following abrupt discontinuance of Inderal therapy. Therefore, when discontinuance of Inderal is planned, the dosage should be gradually reduced over at least a few weeks, and the patient should be cautioned against interruption or cessation of therapy without the physician's advice. If Inderal therapy is interrupted and exacerbation of angina occurs, it usually is advisable to reinstitute Inderal therapy and take other measures appropriate for the management of unstable angina pectoris. Since coronary artery disease may be unrecognized, it may be prudent to follow the above advice in patients considered at risk of having occult atherosclerotic heart disease who are given propranolol for other indications.

Nonallergic Bronchospasm (eg, chronic bronchitis, emphysema) PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD IN GENERAL NOT RECEIVE BETA BLOCKERS. Inderal should be administered with caution since it may block bronchodilation produced by endogenous and exogenous catecholamine stimulation of beta receptors.

MAJOR SURGERY. The necessity or desirability of withdrawal of beta-blocking therapy prior to major surgery is controversial. It should be noted, however, that the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.

Inderal (propranolol HCl), like other beta blockers, is a competitive inhibitor of beta-receptor agonists and its effects can be reversed by administration of such agents, eg, dobutamine or isoproterenol. However, such patients may be subject to protracted severe hypotension. Difficulty in starting and maintaining the heartbeat has also been reported with beta blockers.

DIABETES AND HYPOGLYCEMIA. Beta blockers should be used with caution in diabetic patients if a beta-blocking agent is required. Beta blockers may mask tachycardia occurring with hypoglycemia, but other manifestations such as dizziness and sweating may not be significantly affected. Following insulin-induced hypoglycemia, propranolol may cause a delay in the recovery of blood glucose to normal levels.

THYROTOXICOSIS. Beta blockade may mask certain clinical signs of hyperthyroidism. Therefore, abrupt withdrawal of propranolol may be followed by an exacerbation of symptoms of hyperthyroidism, including thyroid storm. Propranolol may change thyroid function tests, increasing T_4 and reverse T_3 and decreasing T_3 .

IN PATIENTS WITH WOLFF-PARKINSON-WHITE SYNDROME, several cases have been reported in which, after propranolol, the tachycardia was replaced by a severe bradycardia requiring a demand pacemaker. In one case, this resulted after an initial dose of 5 mg propranolol.

PRECAUTIONS. **GENERAL.** Propranolol should be used with caution in patients with impaired hepatic or renal function. Inderal (propranolol HCl) is not indicated for the treatment of hypertensive emergencies.

Beta-adrenoreceptor blockade can cause reduction of intraocular pressure. Patients should

be told that Inderal may interfere with the glaucoma screening test. Withdrawal may lead to a return of increased intraocular pressure.

CLINICAL LABORATORY TESTS. Elevated blood urea levels in patients with severe heart disease, elevated serum transaminase, alkaline phosphatase, lactate dehydrogenase.

DRUG INTERACTIONS. Patients receiving catecholamine-depleting drugs such as reserpine should be closely observed if Inderal is administered. The added catecholamine-blocking action may produce an excessive reduction of resting sympathetic nervous activity which may result in hypotension, marked bradycardia, vertigo, syncopal attacks, or orthostatic hypotension.

Caution should be exercised when patients receiving a beta blocker are administered a calcium-channel-blocking drug, especially intravenous verapamil, for both agents may depress myocardial contractility or atrioventricular conduction. On rare occasions, the concomitant intravenous use of a beta blocker and verapamil has resulted in serious adverse reactions, especially in patients with severe cardiomyopathy, congestive heart failure or recent myocardial infarction.

Aluminum hydroxide gel greatly reduces intestinal absorption of propranolol.

Ethanol slows the rate of absorption of propranolol.

Phenylton, phenobarbital, and rifampin accelerate propranolol clearance.

Chlorpromazine, when used concomitantly with propranolol, results in increased plasma levels of both drugs.

Atipyrine and lidocaine have reduced clearance when used concomitantly with propranolol.

Thyroxine may result in a lower than expected T_3 concentration when used concomitantly with propranolol.

Cimetidine decreases the hepatic metabolism of propranolol, delaying elimination and increasing blood levels.

Theophylline clearance is reduced when used concomitantly with propranolol.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY. Long-term studies in animals have been conducted to evaluate toxic effects and carcinogenic potential. In 18 month studies in both rats and mice, employing doses up to 150 mg/kg/day, there was no evidence of significant drug-induced toxicity. There were no drug-related tumorigenic effects at any of the dosage levels. Reproductive studies in animals did not show any impairment of fertility that was attributable to the drug.

PREGNANCY. Pregnancy Category C. Inderal has been shown to be embryotoxic in animal studies at doses about 10 times greater than the maximum recommended human dose.

There are no adequate and well-controlled studies in pregnant women. Inderal should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

NURSING MOTHERS. Inderal is excreted in human milk. Caution should be exercised when Inderal (propranolol HCl) is administered to a nursing woman.

PEDIATRIC USE. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS. Most adverse effects have been mild and transient and have rarely required the withdrawal of therapy.

Cardiovascular: Bradycardia, congestive heart failure, intensification of AV block, hypotension, paresthesia of hands, thrombocytopenic purpura, arterial insufficiency, usually of the Raynaud type.

Central Nervous System: Light-headedness, mental depression manifested by insomnia, lassitude, weakness, fatigue, reversible mental depression progressing to cataplexy, visual disturbances, hallucinations, vivid dreams, an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics. For immediate formulations, fatigue, lethargy and vivid dreams appear dose related.

Gastrointestinal: Nausea, vomiting, epigastric distress, abdominal cramping, diarrhea, constipation, mesenteric arterial thrombosis, ischemic colitis.

Allergic: Pharyngitis and agranulocytosis, erythematous rash, fever combined with aching and sore throat, laryngospasm and respiratory distress.

Respiratory: Bronchospasm.

Hematologic: Agranulocytosis, nonthrombocytopenic purpura, thrombocytopenic purpura.

Auto-immune: In extremely rare instances, systemic lupus erythematosus has been reported.

Miscellaneous: Alopecia, LE-like reactions, psoriasisiform rashes, dry eyes, male impotence, and Peyronie's disease have been reported rarely. Oculomucocutaneous reactions involving the skin, serous membranes and conjunctivae reported for a beta blocker (practolol) have not been associated with propranolol.

DOSAGE AND ADMINISTRATION. Inderal LA provides propranolol hydrochloride in a sustained-release capsule for administration once daily. If patients are switched from Inderal Tablets to Inderal LA Capsules, care should be taken to assure that the desired therapeutic effect is maintained. Inderal LA should not be considered a simple mg-for-mg substitute for Inderal. Inderal LA has different kinetics and produces lower blood levels. Retitration may be necessary, especially to maintain effectiveness at the end of the 24-hour dosing interval.

HYPERTENSION—Dosage must be individualized. The usual initial dosage is 80 mg Inderal LA once daily, whether used alone or added to a diuretic. The dosage may be increased to 120 mg once daily or higher until adequate blood-pressure control is achieved. The usual maintenance dosage is 120 to 160 mg once daily. In some instances a dosage of 640 mg may be required. The time needed for full hypertensive response to a given dosage is variable and may range from a few days to several weeks.

ANGINA PECTORIS—Dosage must be individualized. Starting with 80 mg Inderal LA once daily, dosage should be gradually increased at three- to seven-day intervals until optimal response is obtained. Although individual patients may respond at any dosage level, the average optimal dosage appears to be 160 mg once daily. In angina pectoris, the value and safety of dosage exceeding 320 mg per day have not been established.

If treatment is to be discontinued, reduce dosage gradually over a period of a few weeks (see WARNINGS).

MIGRAINE—Dosage must be individualized. The initial oral dose is 80 mg Inderal LA once daily. The usual effective dose range is 160-240 mg once daily. The dosage may be increased gradually to achieve optimal migraine prophylaxis. If a satisfactory response is not obtained within four to six weeks after reaching the maximal dose, Inderal LA therapy should be discontinued. It may be advisable to withdraw the drug gradually over a period of several weeks.

HYPERTROPHIC SUBAORTIC STENOSIS—80-160 mg Inderal LA once daily.

PEDIATRIC DOSAGE—At this time the data on the use of the drug in this age group are too limited to permit adequate directions for use.

*The appearance of these capsules is a registered trademark of Ayerst Laboratories.

REFERENCES:

1. Inderal LA National Compliance Evaluation Program. Data on file, Ayerst Laboratories.
2. Ravid M, Lang R, Jutrin I. The relative antihypertensive potency of propranolol, oxprenolol, atenolol, and metoprolol given once daily. *Arch Intern Med* 1985; 145:1321-1323.

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Mrs. Lamar Thomas
A-MASA President

AMA Auxiliary Convention — 1987

In June I attended the annual convention of the AMA Auxiliary in Chicago. Following the model of the AMA our auxiliary reference committees held hearings on many of the current health issues. As a result of these hearings seven resolutions were adopted by the House of Delegates that reflect the concern auxiliaries have for health and safety problems facing America today.

I would like to share with physicians and their spouses the statistics, knowledge and thinking that helped produce these resolutions. In the interest of space and easier reading I will omit the "whereas" and "resolved" that preface every sentence and give you the "meat of the matter." Copies of the original resolutions can be obtained through the AMA Auxiliary in Chicago. Each resolution ends with the resolve that these programs be undertaken with the approval of and in cooperation with the corresponding state and county medical societies/associations. Please keep that in mind as you read the synopsis of the following resolutions.

Education on the Hazards of All-Terrain Vehicles (ATVs). ATV accidents have claimed 644 people and seriously injured approximately 275,000 people. Nearly

half of the casualties involved children under 16 years of age. The design of ATVs makes them unstable as was pointed out in reports from the Consumer Product Safety Commission, the American Academy of Pediatrics and the U.S. Congress. Auxiliaries are asked to participate in education programs concerning the hazards of ATV use by children and the lack of safety factors in ATVs.

Support for Smoke-Free Health Care Facilities. It is the goal of the AMA and the auxiliary to attain a smoke-free society by the year 2000. Health care facilities and physicians should be the role model in the eyes of the nation in the elimination of smoking. Therefore auxiliaries should support programs that eliminate smoking on the premises of hospitals and other health care facilities.

Participation in the AMA Adolescent Health Initiative. The AMA Auxiliary will be represented on the AMA's National Steering Committee on Adolescent Health and will support the AMA's goals to reduce morbidity and mortality in this population group and to help adolescents grow into healthy adults. State and

county auxiliaries are encouraged to implement programs that focus on targeted concerns of adolescents of substance abuse, sexuality and pregnancy, victimization, psychological disorders and suicide, violence/trauma, and the development of healthy lifestyles.

Education on the Importance of Child Water Safety. Drowning is one of the major causes of death for children under five years of age. Near-drowning or submersion accidents can cause children to suffer permanent mental or physical impairment. Auxiliaries should try to participate in educational programs for parents and children that will prevent children from drowning and that will increase water safety consciousness.

Education for the Prevention of Elder Abuse. Elder abuse has been estimated to occur in approximately 10% of Americans over the age of 65 in the areas of physical abuse, neglect, psychological abuse and financial abuse. In most cases the abuser is the family member caretaker. Coping with this dependency relationship can cause the stress that results in abuse. Auxiliaries are asked to establish and/or support existing service and educational programs that encourage the prevention of elder abuse.

Continuation of Seatbelt Education and Support of Mandatory Legislation. Mandatory seatbelt laws have been effective in passing seatbelt laws in 24 states. Seatbelt laws are believed to be an effective means for saving lives, preventing injuries, and relieving the tremendous economic burden that automobile crashes impose. Auxiliaries are encouraged to continue to support seatbelt legislation, educate the public about seatbelt effectiveness, and publicize statistics to demonstrate how lives can be saved and injuries reduced by seatbelt usage.

Promotion of AIDS Education for Youth. There is national concern regarding the epidemic level of Ac-

quired Immune Deficiency Syndrome (AIDS) to all age groups. Though AIDS is preventable through education and changes in personal behavior studies demonstrate that the knowledge base of adolescents in regard to AIDS is limited and inconsistent, indicating the need for health education. The AMA Auxiliary encourages its state and county auxiliaries to recognize the need for and promote the implementation of human sexuality programs following the current policies established by the AMA. These programs must be undertaken with the approval of and in cooperation with the corresponding state and county medical societies/associations.

It was both exciting and rewarding to represent Alabama in the House of Delegates at the AMA Auxiliary Convention. New officers were installed, the budget adopted and motions to change organizational structure were presented. The thing I enjoyed most was being a part of a large group of people from all parts of the U.S., discussing mutual ideas and plans and realizing we were bound together with the unifying thread of supporting better health for all Americans. North, South, East or West — our auxiliary goals are the same. □

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Caution patients about the combined effects of Limbitrol with alcohol or other CNS depressants and about activities requiring complete mental alertness, such as operating machinery or driving a car. In general, limit dosage to the lowest effective amount in elderly patients.

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References: 1. Feighner JP, et al. *Psychopharmacology* 61:217-225, Mar 22, 1979. 2. Data on file, Hoffmann-La Roche Inc., Nutley, NJ

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Tranquillizer—Antidepressant

Before prescribing, please consult complete product information, a summary of which follows:

Indications: Relief of moderate to severe depression associated with moderate to severe anxiety.
Contraindications: Known hypersensitivity to benzodiazepines or tricyclic antidepressants. Do not use with monoamine oxidase (MAO) inhibitors or within 14 days following discontinuation of MAO inhibitors since hyperpyretic crises, severe convulsions and deaths have occurred with concomitant use, then initiate cautiously, gradually increasing dosage until optimal response is achieved. Contraindicated during acute recovery phase following myocardial infarction.

Warnings: Use with great care in patients with history of urinary retention or angle-closure glaucoma. Severe constipation may occur in patients taking tricyclic antidepressants and anticholinergic-type drugs. Closely supervise cardiovascular patients. (Arrhythmias, sinus tachycardia and prolongation of conduction time reported with use of tricyclic antidepressants, especially high doses. Myocardial infarction and stroke reported with use of this class of drugs.) Caution patients about possible combined effects with alcohol and other CNS depressants and against hazardous occupations requiring complete mental alertness (e.g., operating machinery, driving).

Usage in Pregnancy: Use of minor tranquilizers during the first trimester should almost always be avoided because of increased risk of congenital malformations as suggested in several studies. Consider possibility of pregnancy when instituting therapy; advise patients to discuss therapy if they intend to or do become pregnant.

Since physical and psychological dependence to chlordiazepoxide have been reported rarely, use caution in administering Limbitrol to addiction-prone individuals or those who might increase dosage, withdrawal symptoms following discontinuation of either component alone have been reported (nausea, headache and malaise for amitriptyline, symptoms [including convulsions] similar to those of barbiturate withdrawal for chlordiazepoxide).

Precautions: Use with caution in patients with a history of seizures, in hyperthyroid patients or those on thyroid medication, and in patients with impaired renal or hepatic function. Because of the possibility of suicide in depressed patients, do not permit easy access to large quantities in these patients. Periodic liver function tests and blood counts are recommended during prolonged treatment. Amitriptyline component may block action of guanethidine or similar antihypertensives. When tricyclic antidepressants are used concomitantly with cimetidine (Tagamet), clinically significant effects have been reported involving delayed elimination and increasing steady state concentrations of the tricyclic drugs.

Concomitant use of Limbitrol with other psychotropic drugs has not been evaluated, sedative effects may be additive. Discontinue several days before surgery. Limit concomitant administration of ECT to essential treatment. See Warnings for precautions about pregnancy. Limbitrol should not be taken during the nursing period. Not recommended in children under 12. In the elderly and debilitated, limit to smallest effective dosage to preclude ataxia, oversedation, confusion or anticholinergic effects.

Adverse Reactions: Most frequently reported are those associated with either component alone: drowsiness, dry mouth, constipation, blurred vision, dizziness and bloating. Less frequently occurring

reactions include vivid dreams, impotence, tremor, confusion and nasal congestion. Many depressive symptoms including anorexia, fatigue, weakness, restlessness and lethargy have been reported as side effects of both Limbitrol and amitriptyline. Granulocytopenia, jaundice and hepatic dysfunction have been observed rarely.

The following list includes adverse reactions not reported with Limbitrol but requiring consideration because they have been reported with one or both components or closely related drugs: **Cardiovascular:** Hypotension, hypertension, tachycardia, palpitations, myocardial infarction, arrhythmias, heart block, stroke.

Psychiatric: Euphoria, apprehension, poor concentration, delusions, hallucinations, hypomania and increased or decreased libido.

Neurologic: Incoordination, ataxia, numbness, tingling and paresthesias of the extremities, extrapyramidal symptoms, syncope, changes in EEG patterns.

Anticholinergic: Disturbance of accommodation, paralytic ileus, urinary retention, dilatation at urinary tract.

Allergic: Skin rash, urticaria, photosensitization, edema of face and tongue, pruritus.

Hematologic: Bone marrow depression including agranulocytosis, eosinophilia, purpura, thrombocytopenia.

Gastrointestinal: Nausea, epigastric distress, vomiting, anorexia, stomatitis, peculiar taste, diarrhea, black tongue.

Endocrine: Testicular swelling and gynecomastia in the male, breast enlargement, galactorrhea and minor menstrual irregularities in the female, elevation and lowering of blood sugar levels, and syndrome of inappropriate ADH (antidiuretic hormone) secretion.

Other: Headache, weight gain or loss, increased perspiration, urinary frequency, mydriasis, jaundice, alopecia, parotid swelling.

Overdosage: Immediately hospitalize patient suspected of having taken an overdose. Treatment is symptomatic and supportive. IV administration of 1 to 3 mg physostigmine salicylate has been reported to reverse the symptoms of amitriptyline poisoning. See complete product information for manifestation and treatment.

Dosage: Individualize according to symptom severity and patient response. Reduce to smallest effective dosage when satisfactory response is obtained. Larger portion of daily dose may be taken at bedtime. Single h.s. dose may suffice for some patients. Lower dosages are recommended for the elderly. **Limbitrol DS** (double strength) Tablets, initial dosage of three or four tablets daily in divided doses, increased up to six tablets or decreased to two tablets daily as required. **Limbitrol Tablets**, initial dosage of three or four tablets daily in divided doses, for patients who do not tolerate higher dosages.

How Supplied: **Double strength (DS) Tablets**, white, film-coated, each containing 10 mg chlordiazepoxide and 25 mg amitriptyline (as the hydrochloride salt), and **Tablets**, blue, film-coated, each containing 5 mg chlordiazepoxide and 12.5 mg amitriptyline (as the hydrochloride salt). Available in bottles of 100 and 500, Tel-E-Dose[®] packages of 100, Prescription Paks of 50.



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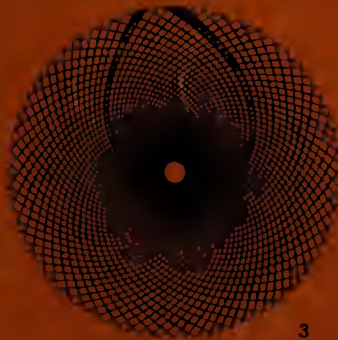
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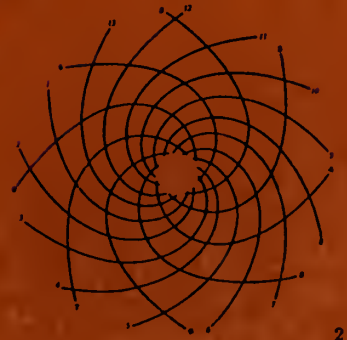


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Nature's Mathematics — page 3

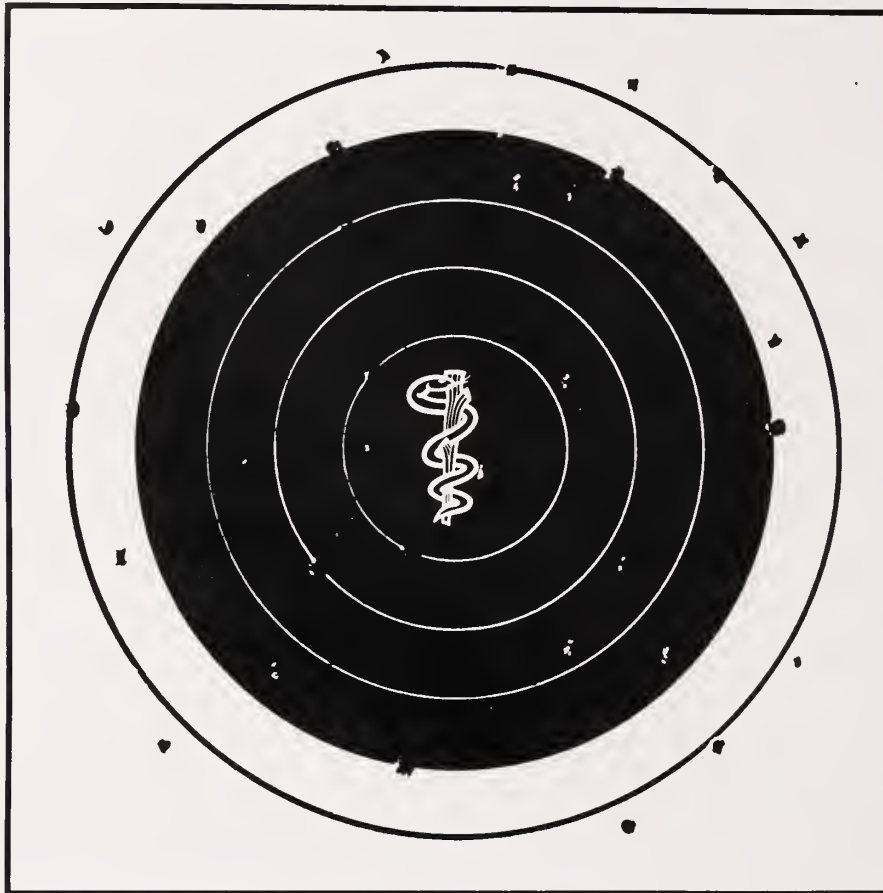


3



2

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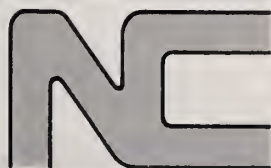
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The Cover

When autumn strips away foliage, nature lovers can see some of the profusion of mathematical forms in underlying structures. The double-helix formation of DNA, for example, has countless other examples in the plant and animal world. The past summer you may have contemplated the logarithmic spiral of some sea shells, another mathematical form that abounds. Less well known (perhaps because the objects are so commonplace) are the Fibonacci sequences of such plants as pineapples, certain cacti, Queen Anne's lace, daisies and others, including the pine cone seen in head-on view (1) on the cover. Named for the most famous mathematician of the Middle Ages, the Fibonacci sequence is the mathematical progression resulting from each term being the sum of the two terms immediately preceding, thus: 1, 1, 2, 3, 5, 8, 13, 21, 34, 55, 89 and so on. Some of the forms in nature may make only selective use of Fibonacci numbers, — say 21 and 55 — while others may employ a lengthy sequence, as in the opposing spirals of the pine cone and sunflower. The pine cone structure is more apparent in its schematic (2) on the cover. The sunflower's schematic is seen in (3). Why? The economy of nature seeks efficient structure. From *Andreas Feininger's Nature and Art*, Dover Publications, New York; Copyright 1983, Feininger.



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Blank space indicates that no such activity has been reported.

Table adapted from Facts and Comparisons (Nov.) 1984 and Catalano RB. The medical approach to management of pain caused by cancer. "Semin Oncol" 1975; 2; 379-92 and Reuler JB, et. al. The chronic pain syndrome: misconceptions and management. "Ann Intern Med" 1980; 93; 588-96.

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Revised, April 1982.

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1. Hopkinson JH III: *Curr Ther Res* 24: 503-516, 1978

2. Beaver, WT *Arch Intern Med*, 141:293-300, 1981.

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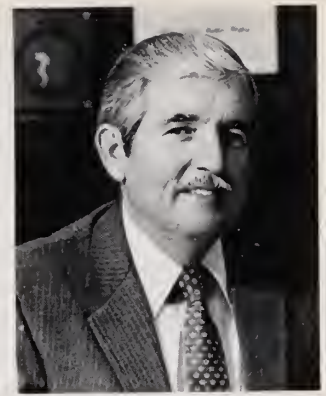
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We Never Had It So Good

Nostalgia, some wag said, ain't what it used to be — a sentence that attacks itself. The late Jackie Gleason said it another way: "The past remembers better than it lived." In other words, the good old days weren't all that good.

Ask most Americans which decade was the best in recent American life and most of them say, according to pollsters, the 1950s. We had just won the great war, prosperity was pretty general in the country, and Americans seemed fairly content with their lives. Expectations were modest.

Many people today believe that they were better off then than now. Although they made few dollars, the dollars they did have went so much further.

True, but not that much further. *Fortune* magazine recently did an in-depth statistical analysis of American life separated by three decades, 1956-86.

Pollster Lou Harris has found that fewer Americans were satisfied with their lives in 1986 than in 1956. *Fortune* wanted to know why.

First, it was necessary to roll out the numbers and do some sophisticated adjusting for inflation. Having established dollars of equal purchasing power for the

two polar years, *Fortune* found that most Americans are better off financially today, by a long chalk, than they were in 1956.

The young, the old, the middle class, even the less advantaged, and indeed the rich too — ALL have made substantial gains despite inflation, oil crises, and all the other tribulations of the intervening years.

Then why do people believe they are not as well off today as in the 1950s? *Fortune* concluded: "We are victims of our expectations." People have come to expect much more than they did then. When they don't get all they want, when they want it, they feel rejected, cheated by the times, a victim of the economy or of somebody's persecution.

Many older Americans remember how, during the 50s, an average family would often wait four or five years before they felt they could buy a TV set. Today, young Americans of the same age feel cheated if they are constrained to wait five weeks for a VCR. Which is another way of repeating the old truism: the perception is the reality.

Fortune found, after digesting all the numbers, this plain truth:

"Prices [since the 50s] have nearly quadrupled, and taxes have been taking a bigger bite since the 50s, but the average American commands twice as much buying power today as in 1952. And per capita income after taxes has been rising in recent years — a third since 1970, and by a tenth just since 1980. The rate of growth since 1970 is only about half the 60s pace, but it matches that of the 50s."

All types of families got richer in the 30 years under study. The typical American family income increased in constant dollars by about 50% between the end of the 50s and last year. Two-income families without children have even more disposable income, because they have fewer people to spend it on. "No children" has replaced the standard two or four for many young couples.

Non-cash benefits help older Americans and lower income in ways not reflected in the figures.

A recent Roper poll found that most Americans believe that it takes an average family \$20,000 to make ends meet, \$30,000 to live moderately well and \$50,000 to achieve the American dream. One in five American families has now achieved the dream compared to one in 20 thirty years ago. But it is among today's well-offs where discontent is more often heard — they expect even more and feel deprived when they don't get it.

At the other end of the spectrum, one in five Americans was classified as poor as the 50s ended. Today, that number is one in ten. They are even better off because of such uncounted benefit programs as food stamps. Additionally, the Michigan Panel found that less than 2% of Americans today could be described as permanently poor.

In health care, the poorest Americans have made the biggest gains, according to Christopher Jencks of Northwestern. More than two-thirds of the poor have some kind of health care today compared with only one-third at the beginning of the 1960s.

In 1986 fully 85% of all Americans have some kind of health coverage, compared with only 70% 25 years ago. Using constant dollars for 1956 and 1986, *Fortune* found that at the average hourly wage, Americans had to work twice as many hours for a man's suit in 1956 as in 1986; 15 minutes of work to pay for a chicken in 1956 compared with six minutes in 1986; 125 hours to buy a kitchen range in 1956, but only 41 hours in 1986. Even haircuts are cheaper now than then in constant dollars.

If Ralph Waldo Emerson was right in his belief that the first wealth is health, *Fortune* continued, Americans are getting even richer. We can expect to live five years longer than in 1960, fewer adults die of heart attacks, and even racial differentials in life expectancies are narrowing. The average white life expectancy today is six years longer than that of blacks,

but the gap was eight years in 1960. *Fortune* concluded that, in health care, Americans "are richer now than ever before."

Automobiles have shot up in price, but it takes the average family 23 weeks of income to buy a median car now, compared with 26 weeks in 1960. And it is hardly the same car. The Ford, Plymouth or Chevy at the end of the 50s had no power steering, no air conditioning, no tape deck, few safety features, and burned a lot more gas. Handling and braking were atrocious by today's standards, yet people can still be heard to say the old cars were better. They weren't. Not by any measure.

The 50s were called the great age of the automobile but the two-car family was a relative rarity then. Today, two- and three-car families make up more than half the total of driving Americans. Back then it was routine for a couple to wait until their middle or late 30s before they could afford their first new car. Today's youngster might wait to 21, but not much beyond that.

A few things *are* less affordable. Many new houses, for example, cost more, in constant dollars, than in the mid-50s. But comparisons are less than precise because many young couples today demand a more luxurious first house than the parents ever dreamed of having.

A visit to the doctor's office is somewhat more expensive, in constant dollars, than in 1956. But, like new cars and new houses, today's medicine is infinitely more sophisticated than in 1956, backed by expensive training and technology scarcely imagined than 30 years ago.

If there is a point to all this, it seems to me it is this: the doctor's image, which most observers agree is less bright than it was in the 1950s, seems to be another victim of extravagant expectations. Americans have had it pretty easy for a long time, in an age when miracles have lost their novelty because they come so often.

The same is true of medicine. So many more Americans survive disease and injury that would have killed them 30 years ago, the public expects miracles 100% of the time.

Additionally, spoiled by decades of payment by government and other third-parties, people feel medical care costs too much if it costs anything at all.

Superb health care, in short, is taken for granted, so is third-party coverage. Out of pocket payment for health care, common in the 1950s, is a rarity for many people today. And, like the yuppies who can't have every new material possession in a week, people feel that somehow health care is a rip-off.

Quoting *Fortune* again: "We are the victims of our own expectations."

Most Americans living today have never known real want. And the generation before them which did re-

member the great depression, is vanishing as a reminder of how it was. The public as now constituted, having never experienced true deprivation of anything, believes the comparative life of ease they enjoy is a given, a starting point only. "I want it all" has become the anthem of a generation.

And when life says to such people that the piper must be paid, they are resentful, longing for the good old days that never were.

Somewhere in this general vicinity I believe is the core problem of the physician image: People expect the moon on a free ticket and are bitter when they can't have it. ◻

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Foods that may help reduce the risk of gastrointestinal and respiratory tract cancer are cabbage, broccoli, brussels sprouts, kohlrabi, cauliflower.

Fruits, vegetables and whole-grain cereals such as oatmeal, bran and wheat may help lower the risk of colorectal cancer.

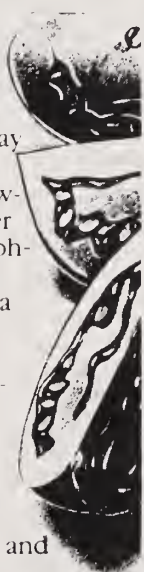
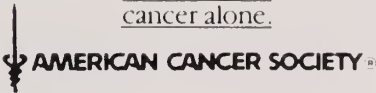
Foods high in fats, salt- or nitrite-cured foods such as ham, and fish and types of sausages smoked by traditional methods should be eaten in moderation.

Be moderate in consumption of alcohol also.

A good rule of thumb is cut down on fat and don't be fat. Weight reduction may lower cancer risk. Our 12-year study of nearly a million Americans uncovered high cancer risks particularly among people 40% or more overweight.

Now, more than ever, we know you can cook up your own defense against cancer. So eat healthy and be healthy.

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*Carl A. Grote, Jr., M.D.
President, MASA*

Will The Real Blue Cross/ Blue Shield Please Stand Up?

My memory of Blue Cross/Blue Shield goes back to the mid-1940s, shortly after World War II, when my father was deeply involved with the Medical Association. In fact, I believe it was during the time my father served his term as President of the Association that Blue Cross/Blue Shield first came into being.

Blue Cross was first enacted by a group from the Hospital Association and the Medical Association. Its primary aim at that time, as I understood it, was to insure that patients would be able to pay their hospital bills and that the hospital would be paid in some fashion.

Blue Shield followed a short time later and MASA was instrumental in forming the first Blue Shield plan in Alabama.

Both of these coverages, Blue Cross/Blue Shield, were primarily indemnity-type plans. They were not fashioned, nor were they intended to be fashioned, in a manner to provide first and last dollar coverage.

Needless to say, I grew up with warm feelings toward Blue Cross/Blue Shield, primarily because my father had warm feelings toward them. He was very proud of the part the Medical Association had played in starting Blue Cross/Blue Shield in Alabama.

My next contact with Blue Cross/Blue Shield came about the time I finished my residency. I was insured by them, they helped pay for the delivery of my second child. The hospital bills by today's standards, were very meager. However, they were there to help me out.

By 1958, when I returned to Huntsville, a fair number of people were insured by Blue Cross/Blue Shield. My father was very proud of the fact that our office group was covered by one of the first contracts issued by Blue Cross/Blue Shield. These policies continued to be of the indemnity type, paying a few dollars for each day in the hospital, only a small part of an appendectomy or tonsillectomy and an equally small part of the hospital stay. Again, Blue Cross/Blue Shield were still known as the doctors' and hospitals' preferred type of coverage. Most of us in those days, when asked what type of policy we would recommend, would recommend Blue Cross/Blue Shield. Aetna, Prudential and other insurance companies were just coming into the forefront.

During this time, as everyone will remember, a large part of the Board of Blue Cross/Blue Shield were hospital administrators and physicians. By their original

continued on page 13

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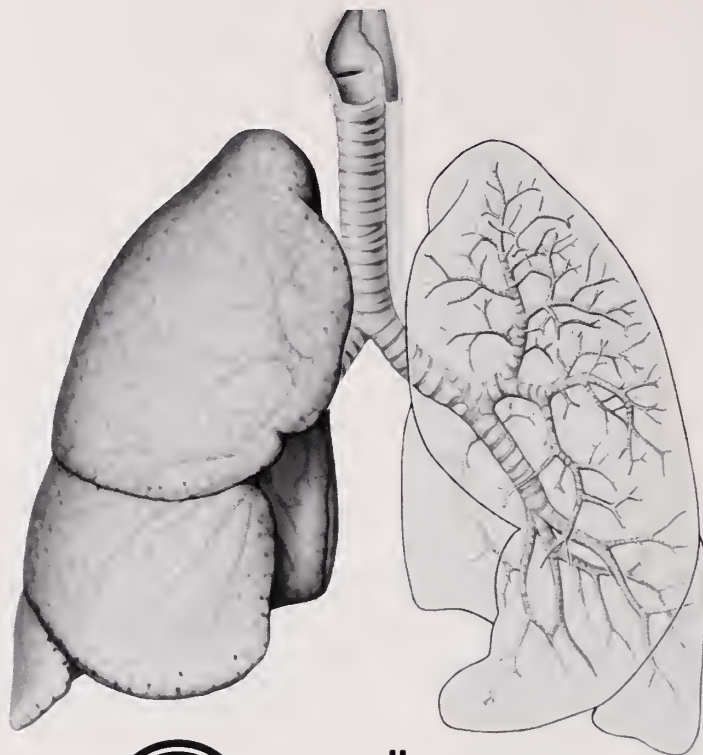
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Haemophilus influenzae, Streptococcus pneumoniae
(ampicillin-susceptible and ampicillin-resistant)

Note: Ceclor is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillin-allergic patients.

Ceclor[®] (cefacior)

Summary. Consult the package literature for prescribing information.

Indications: Lower respiratory infections, including pneumonia, caused by susceptible strains of *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Streptococcus pyogenes* (group A β -hemolytic streptococci).

Contraindication:
Known allergy to cephalosporins.

Warnings:

CECLOR SHOULD BE ADMINISTERED CAUTIOUSLY TO PENICILLIN-SENSITIVE PATIENTS. PENICILLINS AND CEPHALOSPORINS SHOW PARTIAL CROSS-ALLERGENICITY. POSSIBLE REACTIONS INCLUDE ANAPHYLAXIS.

Administer cautiously to allergic patients. Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics. It must be considered in differential diagnosis of antibiotic-associated diarrhea. Colon flora is altered by broad-spectrum antibiotic treatment, possibly resulting in antibiotic-associated colitis.

Precautions:

- Discontinue Ceclor in the event of allergic reactions to it.
- Prolonged use may result in overgrowth of nonsusceptible organisms.
- Positive direct Coombs' tests have been reported during treatment with cephalosporins.
- Ceclor should be administered with caution in the presence of markedly impaired renal function. Although dosage adjustments in moderate to severe renal impairment are usually not required, careful clinical observation and laboratory studies should be made.
- Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.
- Safety and effectiveness have not been determined in pregnancy, lactation, and infants less than one month old. Ceclor penetrates mother's milk. Exercise caution in prescribing for these patients.

Adverse Reactions: (percentage of patients)
Therapy-related adverse reactions are uncommon. Those reported include:

- Gastrointestinal (mostly diarrhea): 2.5%.
- Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment.
- Hypersensitivity reactions (including morbilliform eruptions, pruritus, urticaria, and serum-sickness-like reactions that have included erythema multiforme [rarely, Stevens-Johnson syndrome] or the above skin manifestations accompanied by arthritis/arthritis and, frequently, fever): 1.5%; usually subside within a few days after cessation of therapy. Serum-sickness-like reactions have been reported more frequently in children than in adults and have usually occurred during or following a second course of therapy with Ceclor. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome.
- Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy.
- As with some penicillins and some other cephalosporins, transient hepatitis and cholestatic jaundice have been reported rarely.
- Rarely, reversible hyperactivity, nervousness,

insomnia, confusion, hypertonia, dizziness, and somnolence have been reported.

- Other: eosinophilia, 2%; genital pruritus or vaginitis, less than 1%; and, rarely, thrombocytopenia.

Abnormalities in laboratory results of uncertain etiology

- Slight elevations in hepatic enzymes.
- Transient fluctuations in leukocyte count (especially in infants and children).
- Abnormal urinalysis; elevations in BUN or serum creatinine.
- Positive direct Coombs' test.
- False-positive tests for urinary glucose with Benedict's or Fehling's solution and Clintest[®] tablets but not with Tes-Tape[®] (glucose enzymatic test strip, Lilly).

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charter, it was required that a number of doctors and administrators were in this capacity. Blue Cross/Blue Shield felt obligated to the Hospital Association and the Medical Association. I remember from my early involvement with the Academy of Family Physicians, at one of our annual meetings, Blue Cross/Blue Shield was very much in evidence because physicians were angry with the Blues over some of their policies.

They were there, very apologetic, trying to make friends with all the doctors. During those days, I never went to a large medical meeting when some members of Blue Cross/Blue Shield's executive branch were not there. Bill Miller, then president of Blue Cross/Blue Shield, was always very much in evidence at the annual meetings of the Medical Association.

During the 1960s Medicare and Medicaid came on the scene and Blue Cross/Blue Shield came to be the fiscal intermediary for first Medicare and later, Medicaid. It is my impression then and still is that it was in this period when the doctors began to lose favor with Blue Cross/Blue Shield.

I feel that this was due in large part to the fact that they were administrators for these two federally funded programs. They received a lot of the blame that was not rightly theirs, but belonged in Washington. Nevertheless, many people in both the Hospital Association and the Medical Association began to have their warm feelings replaced by mixed feelings or bad feelings toward Blue Cross/Blue Shield.

In the 1970s when I came on the Board of Censors, the Board was still appointing members to the Blues Board. One of my hopes when I became a Censor was that I would be one of the appointees. Sure enough, I was either the last or one of the last appointees to Blue Cross/Blue Shield. I served in that capacity for several years and resigned at the time I became chairman of the Board of Censors.

The Board meetings of Blue Cross/Blue Shield were not enlightening to me. My memory is that they were relatively sterile and often highlighted by a long and intricate financial report. My main impression of Blue Cross/Blue Shield from these meetings, needless to say, was that here was a large organization that controlled a lot of money and insured a lot of people.

I did get to know many of the executives and I still have friendly feelings toward all of them. Bill Miller, Bill Mandy, Gene Thrasher and Charlie Hartselle I still count as close friends and respect them to the utmost. The most lasting impression from my time with the Blue Cross/Blue Shield came with the claims review committee, made up of physicians on the board. It met prior to the board meetings. This was quite an enlightening experience and something that could well serve many members of the Medical Association.

I think it was through this committee that I came to

appreciate why there was other than good feeling toward physicians. Of course we got the exceptions rather than the rules as far as claims were concerned. Two or three hours in the claims review meetings and one could come away with the distinct impression that doctors were a selfish, money-hungry bunch.

This brings us down to the 1980s. The Medical Association and Blue Cross/Blue Shield seemed to have grown further and further apart. Individual physicians, more and more, seemed to find themselves in an adversarial position with Blue Cross/Blue Shield.

Today we find they are making more demands on our time and energy to help them be more competitive in the market. Certainly Blue Cross/Blue Shield is the most powerful, largest health insurer in the state of Alabama at the present. There is no doubt Blue Cross/Blue Shield has gotten everyone's attention with the PMD program. There are some good aspects and bad aspects to this program. The one thing that can be said about the PMD program for certain is that it is a master job of salesmanship.

I think Blue Cross/Blue Shield should be proud and physicians should take note of just exactly how this was done. First they sold the physicians. They came to primary care physicians, such as myself, offering a fee schedule that was above and beyond what we had been used to. This was particularly true for internists, pediatricians, etc.

They were able to sell this to a large number of physicians with the promise that if you signed up early you would be one of the few doctors that patients would be going to. They were not going to sign up other physicians later, and you would be among the select few.

Of course we all know how long it took them to break that promise. After the physicians were signed up, it was then a simple matter to sell to big industrial entities and the public. It was sold on the basis that the majority of the doctors in the state belong to the PMD program.

Now they had the physicians. Next they had the population. It is my understanding that they cover some 2 million people in Alabama, with promises to cover more.

Now the real Blue Cross comes to the fore. They began to tighten down the program in all aspects, particularly as far as the doctors and hospitals are concerned. They changed the contracts to suit themselves. Of course this goes under the guise that it is all approved by their Advisory Committee.

This leaves some doubt in all our minds about how much of these recommendations really come from that Advisory Committee.

More and more we begin to see the screws tighten down in the PMD program as Blue Cross/Blue Shield seeks to become more competitive and to cover a larger number of people throughout the state. The unfortunate

part of all this is that Blue Cross/Blue Shield seems to have become the advocate of the big customer. It is certainly no longer the advocate of the hospital and the physicians. We begin to see statements by executives of Blue Cross/Blue Shield to the effect that the doctors and hospitals are to blame for the high cost of medical care. Certainly Blue Cross/Blue Shield does not seem to be the patients' advocate as they seem to limit both the amount and the quality of medical care to the contract holders unless it is financially rewarding.

Where does that leave us — with Blue Cross/Blue Shield striving to come out with new programs, such as HMOs, to give them a better share of the market, not only in the field of health insurance but also in life insurance, etc.?

It leaves us tired, frustrated, and upset. We are trying to have meaningful dialogues with a company that no longer chooses to hear. This same company that we helped to form and nurtured for so many, many years, now seems to be our adversary. □

Carl

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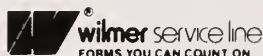
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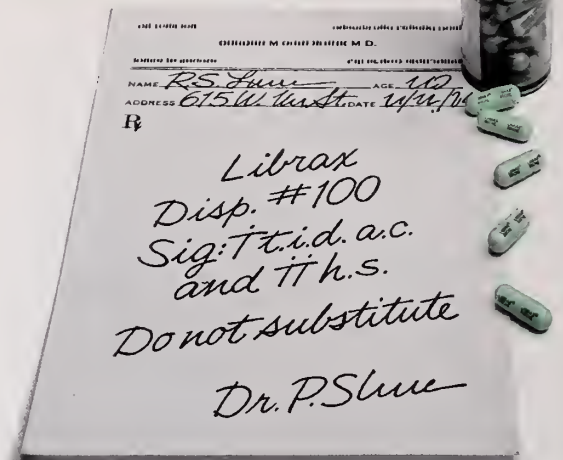


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Usage in Pregnancy: Use of minor tranquilizers during first trimester should almost always be avoided because of increased risk of congenital malformations as suggested in several studies. Consider possibility of pregnancy when instituting therapy. Advise patients to discuss therapy if they intend to or do become pregnant.

As with all anticholinergics, inhibition of lactation may occur. **Precautions:** In elderly and debilitated, limit dosage to smallest effective amount to preclude ataxia, oversedation, confusion (no more than 2 capsules/day initially; increase gradually as needed and tolerated). Though generally not recommended, if combination therapy with other psychotropics seems indicated, carefully consider pharmacology of agents, particularly potentiating drugs such as MAO inhibitors, phenothiazines. Observe usual precautions in presence of impaired renal or hepatic function. Paradoxical reactions reported in psychiatric patients. Employ usual precautions in treating anxiety states with evidence of impending depression; suicidal tendencies may be present and protective measures necessary. Variable effects on blood coagulation reported very rarely in patients receiving the drug and oral anticoagulants; causal relationship not established.

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Tuberculous Pericarditis, A Unique Experience

LeRoy F. Harris, M.D.*

Abstract

Recent reviews of extrapulmonary tuberculosis report a small number and percentage of cases of tuberculous pericarditis but at Huntsville Hospital pericardial disease was our second commonest form of extrapulmonary infection. The pericardium may become infected by contiguous spread from a primary tuberculous pneumonia, hematogenous seeding as a consequence of miliary tuberculosis and direct extension from mediastinal lymph nodes. Pericardial tuberculosis occurs predominately in males 30 to 60 years of age. Often there is an insidious onset of fever, cough, dyspnea and chest pain in association with cardiomegaly, pericardial rub and features of pericardial tamponade. Definitive diagnosis usually requires isolation of *Mycobacterium tuberculosis* from pericardial fluid or tissue. Treatment with antibiotic regimens appropriate for pulmonary tuberculosis, including short-course chemotherapy, is effective. The role of surgical intervention and adjunctive corticosteroid administration is controversial. The prognosis has improved since introduction of antituberculosis chemotherapy and is benefitted by early institution of treatment.

Recent reviews of extrapulmonary tuberculosis have disclosed a small number of cases of tuberculous pericarditis^{1,2} and the most recent series dealing exclusively with patients with tuberculosis of the pericardium was published in 1980.³ At Huntsville Hospital we have been impressed with the relatively frequent occurrence of pericardial tuberculosis in recent years and present our unique experience to reacquaint Alabama physicians with this infection.

Patients and Methods

We reviewed the records of all patients with extrapulmonary tuberculosis discharged from Huntsville Hospital, Huntsville, Alabama, for the six year period, 1981-1986. Extrapulmonary tuberculosis was diagnosed on the basis of isolation of *Mycobacterium tuberculosis* from an extrapulmonary site. The diagnosis of miliary tuberculosis required culture of *M. tuberculosis* from pulmonary secretions and a military pattern on chest roentgenogram. The charts of all patients with tuberculous pericarditis were examined in greater detail.

Results

Table 1 lists 30 cases of extrapulmonary tuberculosis. The most common location was bone and joint closely followed by pericardium and lymph node. Three cases each involved the pleura and genitourinary tract and three cases of miliary tuberculosis were encountered. There were two cases of central nervous system tuberculosis and a single case of tuberculosis of the peritoneum.

continued on page 21

*Clinical Associate Professor of Medicine, School of Primary Medical Care, University of Alabama in Huntsville, 410 Lowell, Huntsville, Alabama 35801.



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References: 1. Feighner JP, et al. *Psychopharmacology* 61:217-225, Mar 22, 1979. 2. Doto on file, Hoffmann-La Roche Inc., Nutley, NJ. 3. Dixon R, Cohen J. *J Clin Psychopharmacol* 3:107-109, Apr 1983

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Indications: Relief of moderate to severe depression associated with moderate to severe anxiety

Contraindications: Known hypersensitivity to benzodiazepines or tricyclic antidepressants. Do not use with monoamine oxidase (MAO) inhibitors or within 14 days following discontinuation of MAO inhibitors since hyperpyretic crises, severe convulsions and deaths have occurred with concomitant use; then initiate cautiously, gradually increasing dosage until optimal response is achieved. Contraindicated during acute recovery phase following myocardial infarction.

Warnings: Use with great care in patients with history of urinary retention or angle-closure glaucoma. Severe constipation may occur in patients taking tricyclic antidepressants and anticholinergic-type drugs. Closely supervise cardiovascular patients (Arrhythmias, sinus tachycardia and prolongation of conduction time reported with use of tricyclic antidepressants, especially high doses. Myocardial infarction and stroke reported with use of this class of drugs.) Caution patients about possible combined effects with alcohol and other CNS depressants and against hazardous occupations requiring complete mental alertness (e.g., operating machinery, driving).

Usage in Pregnancy: Use of minor tranquilizers during the first trimester should almost always be avoided because of increased risk of congenital malformations as suggested in several studies. Consider possibility of pregnancy when instituting therapy; advise patients to discuss therapy if they intend to or do become pregnant.

Since physical and psychological dependence to chlordiazepoxide have been reported rarely, use caution in administering Limbitrol to addiction-prone individuals or those who might increase dosage, withdrawal symptoms following discontinuation of either component alone have been reported (nausea, headache and malaise for amitriptyline; symptoms [including convulsions] similar to those of barbiturate withdrawal for chlordiazepoxide).

Precautions: Use with caution in patients with a history of seizures, in hyperthyroid patients or those on thyroid medication, and in patients with impaired renal or hepatic function. Because of the possibility of suicide in depressed patients, do not permit easy access to large quantities in these patients. Periodic liver function tests and blood counts are recommended during prolonged treatment. Amitriptyline component may block action of guanethidine or similar antihypertensives. When tricyclic antidepressants are used concomitantly with cimetidine (Tagamet), clinically significant effects have been reported involving delayed elimination and increasing steady state concentrations of the tricyclic drugs. Concomitant use of Limbitrol with other psychotropic drugs has not been evaluated, sedative effects may be additive. Discontinue several days before surgery. Limit concomitant administration of ECT to essential treatment. See Warnings for precautions about pregnancy. Limbitrol should not be taken during the nursing period. Not recommended in children under 12. In the elderly and debilitated, limit to smallest effective dosage to preclude ataxia, oversedation, confusion or anticholinergic effects.

Adverse Reactions: Most frequently reported are those associated with either component alone: drowsiness, dry mouth, constipation, blurred vision, dizziness and bloating. Less frequently occurring reactions include vivid dreams, impotence, tremor, confusion and nasal congestion. Many depressive symptoms including anorexia, fatigue, weakness, restlessness and lethargy have been reported as side effects of both Limbitrol and amitriptyline. Granulocytopenia, jaundice and hepatic dysfunction have been observed rarely.

The following list includes adverse reactions not reported with Limbitrol but requiring consideration because they have been reported with one or both components or closely related drugs:

Cardiovascular: Hypotension, hypertension, tachycardia, palpitations, myocardial infarction, arrhythmias, heart block, stroke.

Psychiatric: Euphoria, apprehension, poor concentration, delusions, hallucinations, hypomania and increased or decreased libido.

Neurologic: Incoordination, ataxia, numbness, tingling and paresthesias of the extremities, extrapyramidal symptoms, syncope, changes in EEG patterns.

Anticholinergic: Disturbance of accommodation, paralytic ileus, urinary retention, dilatation of urinary tract.

Allergic: Skin rash, urticaria, photosensitization, edema of face and tongue, pruritus.

Hematologic: Bone marrow depression including agranulocytosis, eosinophilia, purpura, thrombocytopenia.

Gastrointestinal: Nausea, epigastric distress, vomiting, anorexia, stomatitis, peculiar taste, diarrhea, black tongue.

Endocrine: Testicular swelling and gynecomastia in the male, breast enlargement, galactorrhea and minor menstrual irregularities in the female, elevation and lowering of blood sugar levels, and syndrome of inappropriate ADH (antidiuretic hormone) secretion.

Other: Headache, weight gain or loss, increased perspiration, urinary frequency, mydriasis, jaundice, alopecia, parotid swelling.

Overdosage: Immediately hospitalize patient suspected of having taken an overdose. Treatment is symptomatic and supportive. IV administration of 1 to 3 mg physostigmine mesylate has been reported to reverse the symptoms of amitriptyline poisoning. See complete product information for manifestation and treatment.

Dosage: Individualize according to symptom severity and patient response. Reduce to smallest effective dosage when satisfactory response is obtained. Larger portion of daily dose may be taken at bedtime. Single h.s. dose may suffice for some patients. Lower dosages are recommended for the elderly. Limbitrol DS (double strength) Tablets, initial dosage of three or four tablets daily in divided doses, increased up to six tablets or decreased to two tablets daily as required. Limbitrol Tablets, initial dosage of three or four tablets daily in divided doses, for patients who do not tolerate higher doses.

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Table 1
Extrapulmonary Tuberculosis

Bone and joint — 7
Pericardium — 6
Lymph node — 5
Pleura — 3
Genitourinary tract — 3
Miliary — 3
Central nervous system — 2
Peritoneum — 1
Total — 30

Table 2 describes the clinical features of six cases of tuberculous pericarditis. The average age of the patients was 68 years with a range of 51 to 81 years. Four patients were male and two were female. Only two patients possessed underlying illnesses which were breast cancer and alcoholism. Dyspnea was the most frequent complaint followed by fever and cough and less commonly weakness, chest pain and weight loss. The duration of complaints extended from one week to four months and averaged three weeks. The maximum temperature during the first 24 hours of hospitalization ranged from 98.2 to 101.2°F and averaged 99.9°F. The treatment rendered to four patients included pericardiectomy combined with administration of isoniazid (INH), rifampin and ethambutol. One patient underwent pericardial biopsy in addition to receipt of the same three drugs and pericardiocentesis was performed in one patient accompanied by INH, ethambutol and streptomycin administration. All patients survived hospitalization for a zero per cent mortality rate.

Table 3 highlights the diagnostic studies performed in six patients with tuberculosis of the pericardium. The leukocyte count on admission to the hospital extended from 4600 to 9600 per cu mm and averaged 6950 per cu mm. The chest roentgenogram on admission to the hospital disclosed cardiomegaly in three patients, pleural effusions in four patients and atelectasis in one patient and was normal in one patient. The results of the PPD intermediate strength skin test were positive in four patients and negative in two patients. Histologic examination of the pericardium demonstrated granulomas in four patients and acid fast bacilli in three patients and by definition *M. tuberculosis* was isolated from all five specimens. Acid fast bacilli were not visualized microscopically and again by definition *M. tuberculosis* was cultured from pericardial fluid in the single patient subjected to pericardiocentesis.

Discussion

Although there has been a reduction in the number of new cases of pulmonary tuberculosis during the past

20 years, the number of newly reported cases of extrapulmonary tuberculosis has remained constant at approximately 4000 per year with a resulting increased percentage of cases of extrapulmonary tuberculosis. Proposed explanations for the continuing prevalence of extrapulmonary tuberculosis include increased recognition and reporting of extrapulmonary cases, erroneous diagnosis of extrapulmonary tuberculosis and increased frequency of extrapulmonary disease.¹

Two recent reviews of extrapulmonary tuberculosis reported a low incidence of zero to five per cent of cases of pericardial infection. In contrast, our experience demonstrates that tuberculous pericarditis is the second most common location of extrapulmonary disease with a 20 percent incidence and an average of one case per year.

The pathogenesis of pericardial tuberculosis involves three possible mechanisms. The pericardium may be infected by contiguous spread from a primary tuberculous pneumonia which usually occurs in children. There also may be progressive multiplication of organisms at foci of metastatic localization as a consequence of miliary tuberculosis. This situation is found in young children and immunosuppressed or debilitated hosts and the pericardial disease usually is overshadowed by involvement of other organs. Most frequently tuberculous pericarditis results from breakdown of latent infection in mediastinal lymph nodes with extension directly into the pericardium. Less often extension arises from reactivation of pleural or rib disease. In this situation pericardial infection is the only clinically apparent manifestation.⁴

The clinical manifestations of pericardial tuberculosis are varied and are related to the extent of pericardial involvement as well as concomitant extrapericardial disease. The majority of patients are between 30 and 60 years of age with males comprising over 75 per cent of cases. The onset usually is insidious over weeks to months but may be acute and fulminant in up to 25 per cent of cases. The most common symptoms are cough, dyspnea, chest pain, night sweats, orthopnea, weight loss and ankle edema. Frequent clinical findings include fever, tachycardia, cardiomegaly, pericardial rub and features of pericardial tamponade such as paradoxical pulse, neck vein distention, hepatomegaly, pleural effusion and edema.⁵ In our series the patients were elderly and two-thirds were male. The onset was subacute to chronic and common clinical features consisted of fever, cough, dyspnea and chest pain.

Although the anatomic diagnosis of pericarditis with effusion, tamponade or constriction can be verified readily by physical examination, echocardiography and hemodynamic monitoring, establishing the etiology as tuberculous in origin often is problematical. Routine laboratory studies are not helpful⁶ as evidenced by a normal leukocyte count in our patients. The chest

Table 2
Tuberculous Pericarditis — Clinical Features

Patient No.	Age (years)	Sex	Underlying Illness	Chief Complaint — Duration	Temperature* (°F)	Treatment	Outcome
1	81	M	None	Fever, weakness, cough — 4 months	101.2	Pericardiectomy INH + , rifampin, ethambutol	Live
2	70	F	Breast Cancer	Fever, cough, dyspnea — 2 weeks	100.2	Pericardiectomy INH, rifampin ethambutol	Live
3	51	M	None	Chest pain, weight loss — 1 month	99.4	Pericardiectomy INH, rifampin, ethambutol	Live
4	75	M	None	Fever, cough, dyspnea — 3 weeks	100.2	Pericardial biopsy INH, rifampin, ethambutol	Live
5	63	F	None	Dyspnea, chest pain — 4 months	98.2	Pericardiectomy INH, rifampin ethambutol	Live
6	65	M	Alcoholism	Weakness, dyspnea — 1 week	100.4	Pericardiocentesis INH, ethambutol, streptomycin	Live

* Maximum temperature during first 24 h of hospitalization.

† Isoniazid

x-ray is abnormal in over 50 per cent of patients and the tuberculin skin test is reactive in nearly 90 per cent of cases.¹ In our patients pleural effusion and cardiomegaly represented the commonest chest roentgenogram findings while the skin test was positive in two-thirds of patients.

Although some authorities accept the diagnosis of tuberculous pericarditis in patients with a compatible history, pericardial effusion and positive skin test⁴ or in patients with a pericardial effusion and an associated tuberculous focus of infection,⁵ definitive diagnosis usually requires isolation of *M. tuberculosis* from pericardial fluid or tissue. Pericardial fluid obtained by pericardiocentesis is exudative and acid fast organisms rarely are detected by smear but *M. tuberculosis* is grown in up to 40 per cent of cases.⁵ Because of its inherent risks and limited diagnostic usefulness, pericardiocentesis infrequently is performed today. Instead, open pericardial biopsy utilizing a subxiphoid approach has emerged as the diagnostic procedure of choice.⁶ In our cases acid fast organisms were not visualized on smear from pericardial fluid but along with granulomas were seen in 60 per cent of pericardial biopsies. By definition all cultures yielded *M. tuberculosis*.

The treatment of pericardial tuberculosis involves three issues of which two are controversial. There is uniform agreement that antibiotic therapy is the same for pericarditis as for pulmonary tuberculosis⁶ and recent evidence suggests that short-course chemotherapy

is as effective for extrapulmonary (including pericardial) tuberculosis as it is for pulmonary infection.⁷ For newly diagnosed and drug-susceptible disease the following regimen is advocated: isoniazid, 300 mg, and rifampin, 600 mg, daily for one month following by isoniazid, 900 mg and rifampin, 600 mg, twice weekly for another eight months. For suspected drug-resistant cases, treatment is started with streptomycin, 0.5 to 1 g five days a week and isoniazid, 300 mg, rifampin, 600 mg, and pyrazinamide, 25 to 30 mg per kg body weight, daily for two months followed by streptomycin, 1 g, pyrazinamide, 45 to 50 mg per kg body weight, and depending on drug susceptibility tests isoniazid, 900 mg, or rifampin, 600 mg, twice weekly for an additional seven months.⁷

Lack of consensus surrounds the role of surgical intervention and the administration of adjunctive corticosteroids. Most authorities advocate pericardiectomy when the diagnosis is uncertain and for persistent cardiomegaly, progressive congestive heart failure and rising venous pressure with a reduction in heart size.⁵ In addition, some groups recommend surgery following institution of chemotherapy for all reasonable risk patients because of reduced morbidity and mortality with pericardiectomy versus medical therapy alone.^{3, 8} Surgery should be prompt to prevent constriction and because it is technically easier to perform before fibrosis supervenes.⁵

Treatment with corticosteroids is postulated to diminish cardiovascular complications of acute pericar-

Table 3
Tuberculous Pericarditis — Diagnostic Studies

Case No.	WBC* (cells/ cu mm)	Chest X-ray†	PPD Intermediate Strength	Pericardium		
				Granulomas‡	AFB Smear§	Culture
1	5700	Cardiomegaly, L pleural effusion	Negative	Yes	Yes	Yes
2	7700	Bilateral pleural effusions	Positive	Yes	No	Yes
3	8500	Bilateral pleural effusions	Positive	Yes	Yes	Yes
4	9600	Cardiomegaly, atelectasis L base	Positive	No	No	Yes
5	4600	Normal	Positive	Yes	Yes	Yes
Pericardial Fluid						
6	5600	Cardiomegaly, R pleural effusion	Negative	—	No	Yes

* Leukocyte count on admission to hospital

† Chest x-ray on admission to hospital

‡ Granulomas visualized by histologic examination of pericardium.

§ Acid fast bacilli visualized by histologic examination of pericardium or pericardial fluid

|| *Mycobacterium tuberculosis* recovered from culture of pericardium or pericardial fluid

dial infection and prevent constriction by suppressing inflammation and enhancing reabsorption of the effusion. One series documented less mortality and requirement for pericardiectomy in patients treated with antituberculous chemotherapy and corticosteroids as compared to patients administered chemotherapy alone. The regimen of corticosteroids utilized was prednisone, 80 mg, daily tapered over a six to eight week period.⁹ Corticosteroids should be used only when the etiologic diagnosis is secure and surgery is not performed.⁶ In our experience pericardiectomy was undertaken in four patients and corticosteroids were not used.

The prognosis of tuberculosis of the pericardium was poor prior to the introduction of antituberculous chemotherapy with a mortality rate approaching 90 per cent.⁵ More recent data disclosed an over-all fatality rate of 31 per cent which decreased to 14 per cent with adequate treatment.⁹ The prognosis is benefitted by early institution of appropriate chemotherapy.¹⁰ In our series there were no fatalities. □

Acknowledgement

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This drug is not indicated for initial therapy of edema or hypertension. Edema or hypertension requires therapy titrated to the individual. If this combination represents the dosage so determined, its use may be more convenient in patient management. Treatment of hypertension and edema is not static, but must be reevaluated as conditions in each patient warrant.

Contraindications: Concomitant use with other potassium-sparing agents such as spironolactone or amiloride. Further use in anuria, progressive renal or hepatic dysfunction, hyperkalemia. Pre-existing elevated serum potassium. Hypersensitivity to either component or other sulfonamide-derived drugs.

Warnings: Do not use potassium supplements, dietary or otherwise, unless hypokalemia develops or dietary intake of potassium is markedly impaired. If supplementary potassium is needed, potassium tablets should not be used. Hyperkalemia can occur, and has been associated with cardiac irregularities. It is more likely in the severely ill, with urine volume less than one liter/day, the elderly and diabetics with suspected or confirmed renal insufficiency. Periodically, serum K⁺ levels should be determined. If hyperkalemia develops, substitute a thiazide alone, restrict K⁺ intake. Associated widened QRS complex or arrhythmia requires prompt additional therapy. Thiazides cross the placental barrier and appear in cord blood. Use in pregnancy requires weighing anticipated benefits against possible hazards, including fetal or neonatal jaundice, thrombocytopenia, other adverse reactions seen in adults. Thiazides appear and triamterene may appear in breast milk. If their use is essential, the patient should stop nursing. Adequate information on use in children is not available. Sensitivity reactions may occur in patients with or without a history of allergy or bronchial asthma. Possible exacerbation or activation of systemic lupus erythematosus has been reported with thiazide diuretics.

Precautions: The bioavailability of the hydrochlorothiazide component of 'Dyazide' is about 50% of the bioavailability of the single entity. Theoretically, a patient transferred from the single entities of triamterene and hydrochlorothiazide may show an increase in blood pressure or fluid retention. Similarly, it is also possible that the lesser hydrochlorothiazide bioavailability could lead to increased serum potassium levels. However, extensive clinical experience with 'Dyazide' suggests that these conditions have not been commonly observed in clinical practice. Angiotensin-converting enzyme (ACE) inhibitors can elevate serum potassium; use with caution with 'Dyazide'. Do periodic serum electrolyte determinations (particularly important in patients vomiting excessively or receiving parenteral fluids, and during concurrent use with amphotericin B or corticosteroids or corticotropin [ACTH]). Periodic BUN and serum creatinine determinations should be made, especially in the elderly, diabetics or those with suspected or confirmed renal insufficiency. Cumulative effects of the drug may develop in patients with impaired renal function. Thiazides should be used with caution in patients with impaired hepatic function. They can precipitate coma in patients with severe liver disease. Observe regularly for possible blood dyscrasias, liver damage, other idiosyncratic reactions. Blood dyscrasias have been reported in patients receiving triamterene, and leukopenia, thrombocytopenia, agranulocytosis, and aplastic and hemolytic anemia have been reported with thiazides. Thiazides may cause manifestation of latent diabetes mellitus. The effects of oral anticoagulants may be decreased when used concurrently with hydrochlorothiazide; dosage adjustments may be necessary. Clinically insignificant reductions in arterial responsiveness to norepinephrine have been reported. Thiazides have also been shown to increase the paralyzing effect of nondepolarizing muscle relaxants such as tubocurarine. Triamterene is a weak folic acid antagonist. Do periodic blood studies in cirrhotics with splenomegaly. Antihypertensive effects may be enhanced in post-sympathectomy patients. Use cautiously in surgical patients. Triamterene has been found in renal stones in association with the other usual calculus components. Therefore, 'Dyazide' should be used with caution in patients with histories of stone formation. A few occurrences of acute renal failure have been reported in patients on 'Dyazide' when treated with indomethacin. Therefore, caution is advised in administering nonsteroidal anti-inflammatory agents with 'Dyazide'. The following may occur: transient elevated BUN or creatinine or both, hyperglycemia and glycosuria (diabetic insulin requirements may be altered), hyperuricemia and gout, digitalis intoxication (in hypokalemia), decreasing alkali reserve with possible metabolic acidosis. 'Dyazide' interferes with fluorescent measurement of quinidine. Hypokalemia is uncommon with 'Dyazide', but should it develop, corrective measures should be taken such as potassium supplementation or increased dietary intake of potassium-rich foods. Corrective measures should be instituted cautiously and serum potassium levels determined. Discontinue corrective measures and 'Dyazide' should laboratory values reveal elevated serum potassium. Chloride deficit may occur as well as dilutional hyponatremia. Concurrent use with chlorpropamide may increase the risk of severe hyponatremia. Serum PBI levels may decrease without signs of thyroid disturbance. Calcium excretion is decreased by thiazides. 'Dyazide' should be withdrawn before conducting tests for parathyroid function. Thiazides may add to or potentiate the action of other anti-hypertensive drugs. Diuretics reduce renal clearance of lithium and increase the risk of lithium toxicity.

Adverse Reactions: Muscle cramps, weakness, dizziness, headache, dry mouth; anaphylaxis, rash, urticaria, photosensitivity, purpura, other dermatological conditions; nausea and vomiting, diarrhea, constipation, other gastrointestinal disturbances; postural hypotension (may be aggravated by alcohol, barbiturates, or narcotics). Necrotizing vasculitis, paresthesias, icterus, pancreatitis, xanthopsia and respiratory distress including pneumonitis and pulmonary edema, transient blurred vision, sialadenitis, and vertigo have occurred with thiazides alone. Triamterene has been found in renal stones in association with other usual calculus components. Rare incidents of acute interstitial nephritis have been reported. Impotence has been reported in a few patients on 'Dyazide', although a causal relationship has not been established.

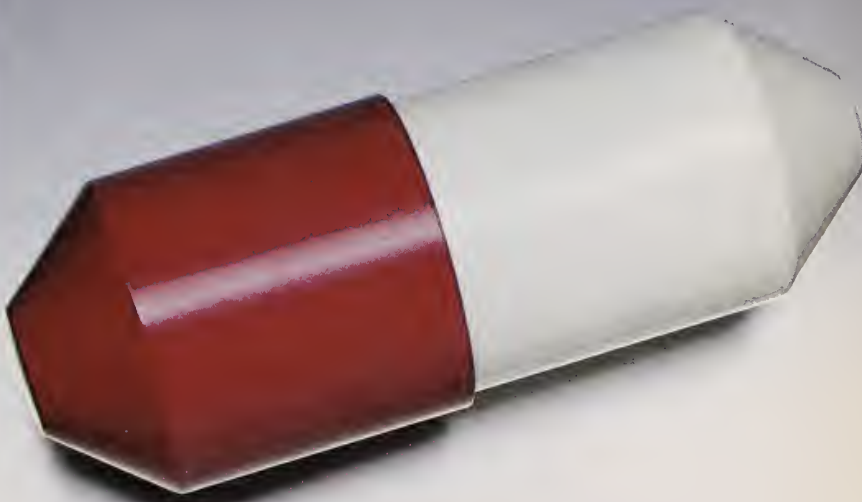
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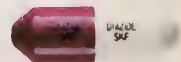
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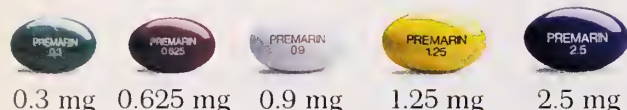
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*PREMARIN is indicated for moderate-to-severe vasomotor symptoms

Please see following page for brief summary
of prescribing information.

For moderate-to-severe
vasomotor symptoms and
for osteoporosis

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BRIEF SUMMARY (FOR FULL PRESCRIBING INFORMATION AND PATIENT INFORMATION, SEE PACKAGE CIRCULARS)

PREMARIN® Brand of conjugated estrogens tablets, USP
PREMARIN® Brand of conjugated estrogens Vaginal Cream, in a nonliquefying base

1 ESTROGENS HAVE BEEN REPORTED TO INCREASE THE RISK OF ENDOMETRIAL CARCINOMA

Three independent, case-controlled studies have reported an increased risk of endometrial cancer in postmenopausal women exposed to exogenous estrogens for more than one year. This risk was independent of the other known risk factors for endometrial cancer. These studies are further supported by the finding that incidence rates of endometrial cancer have increased sharply since 1969 in eight different areas of the United States with population-based cancer reporting systems, an increase which may be related to the rapidly expanding use of estrogens during the last decade. The three case-controlled studies reported that the risk of endometrial cancer in estrogen users was about 4.5 to 13.9 times greater than in nonusers. The risk appears to depend on both duration of treatment and on estrogen dose. In view of these findings, when estrogens are used for the treatment of menopausal symptoms, the lowest dose that will control symptoms should be utilized and medication should be discontinued as soon as possible. When prolonged treatment is medically indicated, the patient should be reassessed on at least a semi-annual basis to determine the need for continued therapy. Although the evidence must be considered preliminary, one study suggests that cyclic administration of low doses of estrogen may carry less risk than continuous administration, it therefore appears prudent to utilize such a regimen. Close clinical surveillance of all women taking estrogens is important. In all cases of undiagnosed persistent or recurring abnormal vaginal bleeding, adequate diagnostic measures should be undertaken to rule out malignancy. There is no evidence at present that "natural" estrogens are more or less hazardous than "synthetic" estrogens at equi-estrogenic doses.

2 ESTROGENS SHOULD NOT BE USED DURING PREGNANCY

The use of female sex hormones, both estrogens and progestogens, during early pregnancy may seriously damage the offspring. It has been shown that females exposed in utero to diethylstilbestrol, a nonsteroidal estrogen, have an increased risk of developing, in later life, a form of vaginal or cervical cancer that is ordinarily extremely rare. This risk has been estimated as not greater than 4 per 1,000 exposures. Furthermore, a high percentage of such exposed women (from 30% to 90%) have been found to have vaginal adenosis, epithelial changes of the vagina and cervix. Although these changes are histologically benign, it is not known whether they are precursors of malignancy. Although similar data are not available with the use of other estrogens, it cannot be presumed they would not induce similar changes. Several reports suggest an association between intrauterine exposure to female sex hormones and congenital anomalies, including congenital heart defects and limb-reduction defects. One case-controlled study estimated a 4.7-fold increased risk of limb-reduction defects in infants exposed in utero to sex hormones (oral contraceptives, hormone withdrawal tests for pregnancy, or attempted treatment for threatened abortion). Some of these exposures were very short and involved only a few days of treatment. The data suggest that the risk of limb-reduction defects in exposed fetuses is somewhat less than 1 per 1,000. In the past, female sex hormones have been used during pregnancy in an attempt to treat threatened or habitual abortion. There is considerable evidence that estrogens are ineffective for these indications, and there is no evidence from well-controlled studies that progestogens are effective for these uses. If PREMARIN is used during pregnancy or if the patient becomes pregnant while taking this drug, she should be apprised of the potential risks to the fetus, and the advisability of pregnancy continuation.

DESCRIPTION: PREMARIN (conjugated estrogens, USP) contains a mixture of estrogens, obtained exclusively from natural sources, blended to represent the average composition of material derived from pregnant mares' urine. It contains estrone, equilin, and 17 α -dihydroequilin, together with smaller amounts of 17 α -estradiol, equilenin, and 17 α -dihydroequilenin as salts of their sulfate esters. Tablets are available in 0.3 mg, 0.625 mg, 0.9 mg, 1.25 mg, and 2.5 mg strengths of conjugated estrogens. Cream is available as 0.625 mg conjugated estrogens per gram.

INDICATIONS AND USAGE: PREMARIN (conjugated estrogens tablets, USP). Moderate-to-severe vasomotor symptoms associated with the menopause. (There is no evidence that estrogens are effective for nervous symptoms or depression without associated vasomotor symptoms and they should not be used to treat such conditions.) Osteoporosis (abnormally low bone mass). Atrophic vaginitis. Kraurosis vulvae. Female castration. PREMARIN (conjugated estrogens) Vaginal Cream is indicated in the treatment of atrophic vaginitis and kraurosis vulvae.

PREMARIN HAS NOT BEEN SHOWN TO BE EFFECTIVE FOR ANY PURPOSE DURING PREGNANCY AND ITS USE MAY CAUSE SEVERE HARM TO THE FETUS (SEE BOXED WARNING).

Concomitant Progestin Use: The lowest effective dose appropriate for the specific indication should be utilized. Studies of the addition of a progestin for 7 or more days of a cycle of estrogen administration have reported a lowered incidence of endometrial hyperplasia. Morphological and biochemical studies of the endometrium suggest that 10 to 13 days of progestin are needed to provide maximal maturation of the endometrium and to eliminate any hyperplastic changes. Whether this will provide protection from endometrial carcinoma has not been clearly established. There are possible additional risks which may be associated with the inclusion of progestin in estrogen replacement regimens (See PRECAUTIONS). The choice of progestin and dosage may be important; product labeling should be reviewed to minimize possible adverse effects.

CONTRAINDICATIONS: Estrogens should not be used in women (or men) with any of the following conditions: 1. Known or suspected cancer of the breast except in appropriately selected patients being treated for metastatic disease. 2. Known or suspected estrogen-dependent neoplasia. 3. Known or suspected pregnancy (see Boxed Warning). 4. Undiagnosed abnormal genital bleeding. 5. Active thrombophlebitis or thromboembolic disorders. 6. A past history of thrombophlebitis, thrombosis, or thromboembolic disorders associated with previous estrogen use (except when used in treatment of breast or prostatic malignancy).

WARNINGS: Estrogens have been reported to increase the risk of endometrial carcinoma (see Boxed Warning). However, a recent large, case-controlled study indicated no increase in risk of breast cancer in postmenopausal women. A recent study has reported a 2- to 3-fold increase in the risk of surgically confirmed gallbladder disease in women receiving postmenopausal estrogens.

Adverse effects of oral contraceptives may be expected at the larger doses of estrogen used to treat prostatic or breast cancer or postpartum breast engorgement, it has been shown that there is an increased risk of thrombosis in men receiving estrogens for prostatic cancer and women for postpartum breast engorgement. Users of oral contraceptives have an increased risk of diseases, such as thrombophlebitis, pulmonary embolism, stroke, and myocardial infarction. Cases of retinal thrombosis, mesenteric thrombosis, and optic neuritis have been reported in oral contraceptive users. An increased risk of postsurgery thromboembolic complications has also been reported in users of oral contraceptives. If feasible, estrogen should be discontinued at least 4 weeks before surgery of the type associated with an increased risk of thromboembolism, or during periods of prolonged immobilization. Estrogens should not be used in persons with active thrombophlebitis, thromboembolic disorders, or in persons with a history of such disorders in association with estrogen use. They should be used with caution in patients with cerebral vascular or coronary artery disease. Large doses (5 mg conjugated estrogens per day), comparable to those used to treat cancer of the prostate and breast, have been shown to increase the risk of nonfatal myocardial infarction, pulmonary embolism, and thrombophlebitis. When doses of this size are used, any of the thromboembolic and thrombotic adverse effects should be considered a clear risk.

For atrophic vaginitis

PREMARIN® (conjugated estrogens)

Vaginal
Cream
0.625 mg/g



Benign hepatic adenomas should be considered in estrogen users having abdominal pain and tenderness, abdominal mass, or hypovolemic shock. Hepatocellular carcinoma has been reported in women taking estrogen-containing oral contraceptives. Increased blood pressure may occur with use of estrogens in the menopause and blood pressure should be monitored with estrogen use. A worsening of glucose tolerance has been observed in patients on estrogen-containing oral contraceptives. For this reason, diabetic patients should be carefully observed. Estrogens may lead to severe hypercalcemia in patients with breast cancer and bone metastases.

PRECAUTIONS: Physical examination and a complete medical and family history should be taken prior to the initiation of any estrogen therapy with special reference to blood pressure, breasts, abdomen, and pelvic organs, and should include a Papanicolaou smear. As a general rule, estrogen should not be prescribed for longer than one year without another physical examination being performed. Conditions influenced by fluid retention, such as asthma, epilepsy, migraine, and cardiac or renal dysfunction, require careful observation. Certain patients may develop manifestations of excessive estrogenic stimulation, such as abnormal or excessive uterine bleeding, mastodynia, etc. Prolonged administration of unopposed estrogen therapy has been reported to increase the risk of endometrial hyperplasia in some patients. Oral contraceptives appear to be associated with an increased incidence of mental depression. Patients with a history of depression should be carefully observed. Pre-existing uterine leiomyomata may increase in size during estrogen use. The pathologist should be advised of estrogen therapy when relevant specimens are submitted. If jaundice develops in any patient receiving estrogen, the medication should be discontinued while the cause is investigated. Estrogens should be used with care in patients with impaired liver function, renal insufficiency, metabolic bone diseases associated with hypercalcemia or in young patients in whom bone growth is not yet complete. If concomitant progestin therapy is used, potential risks may include adverse effects on carbohydrate and lipid metabolism.

The following changes may be expected with larger doses of estrogen:
a. Increased sulfobromophthalen retention
b. Increased prothrombin and factors VII, VIII, IX, and X, decreased antithrombin 3, increased norepinephrine-induced platelet aggregability
c. Increased thyroid binding globulin (TBG) leading to increased circulating total thyroid hormone, as measured by PBI, T_4 by column, or T_4 by radioimmunoassay. Free T_3 resin uptake is decreased, reflecting the elevated TBG; free T_4 concentration is unaltered.
d. Impaired glucose tolerance
e. Decreased pregnanediol excretion
f. Reduced response to methylparathion test
g. Reduced serum iodine concentration
h. Increased serum triglyceride and phospholipid concentration

As a general principle, the administration of any drug to nursing mothers should be done only when clearly necessary since many drugs are excreted in human milk.

Long-term, continuous administration of natural and synthetic estrogens in certain animal species increases the frequency of carcinomas of the breast, cervix, vagina, and liver. However, in a recent, large case-controlled study of postmenopausal women there was no increase in risk of breast cancer with use of conjugated estrogens.

ADVERSE REACTIONS: The following have been reported with estrogenic therapy including oral contraceptives, breakthrough bleeding, spotting, change in menstrual flow, dysmenorrhea, premenstrual-like syndrome, amenorrhea during and after treatment, increase in size of uterine fibromyoma, vaginal candidiasis, change in cervical erosion and in degree of cervical secretion, cystitis-like syndrome, tenderness, enlargement, secretion (of breasts), nausea, vomiting, abdominal cramps, bloating, cholestatic jaundice, chloasma or melasma which may persist when drug is discontinued, erythema multiforme, erythema nodosum, hemorrhagic eruption, loss of scalp hair, hirsutism, steepening of corneal curvature, intolerance to contact lenses, headache, migraine, dizziness, mental depression, chorea, increase or decrease in weight, reduced carbohydrate tolerance, aggravation of porphyria, edema, changes in libido.

ACUTE OVERDOSAGE: May cause nausea, and withdrawal bleeding may occur in females.

DOSEAGE AND ADMINISTRATION:

PREMARIN® Brand of conjugated estrogens tablets, USP

1. Given cyclically for short-term use only. For treatment of moderate-to-severe vasomotor symptoms, atrophic vaginitis, or kraurosis vulvae associated with the menopause (0.3 mg to 1.25 mg or more daily). The lowest dose that will control symptoms should be chosen and medication should be discontinued as promptly as possible. Administration should be cyclic (eg, three weeks on and one week off). Attempts to discontinue or taper medication should be made at three- to six-month intervals.
2. Given cyclically. Osteoporosis. Female castration. Osteoporosis — 0.625 mg daily. Administration should be cyclic (eg, three weeks on and one week off). Female castration — 1.25 mg daily, cyclically. Adjust upward or downward according to response of the patient. For maintenance, adjust dosage to lowest level that will provide effective control.

Patients with an intact uterus should be monitored for signs of endometrial cancer and appropriate measures taken to rule out malignancy in the event of persistent or recurring abnormal vaginal bleeding.

PREMARIN® Brand of conjugated estrogens Vaginal Cream

Given cyclically for short-term use only. For treatment of atrophic vaginitis or kraurosis vulvae.

The lowest dose that will control symptoms should be chosen and medication should be discontinued as promptly as possible.

Administration should be cyclic (eg, three weeks on and one week off). Attempts to discontinue or taper medication should be made at three- to six-month intervals. Usual dosage range: 2 g to 4 g daily intravaginally, depending on the severity of the condition.

Treated patients with an intact uterus should be monitored closely for signs of endometrial cancer and appropriate diagnostic measures should be taken to rule out malignancy in the event of persistent or recurring abnormal vaginal bleeding.

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The Use of Positive Inotropic Agents in Chronic Left Ventricular Failure: Time for Reflection

Silvio E. Papapietro, M.D.*

"At times, scientific progress depends less upon acquisition of new knowledge than upon the removal of conceptual obstacles."

— Rushmer, 1963

Heart failure, the leading cause of cardiac death, frequently is the end-result of abnormal left ventricular function. Left ventricular dysfunction may be related to various etiologies, including ischemia, chronic pressure or volume overload, and inflammation. Disease and chronic overload impair systolic ventricular function, reducing the force and extent of myocardial contraction, and stroke volume. Compensatory ventricular dilatation tends to return stroke volume to baseline. Dilatation increases myocardial energy requirements and the force the ventricle has to develop during ejection ("afterload"), and further impairs systolic function. Ventricular dysfunction may also be manifested by diastolic abnormalities, with reduction in the rate of relaxation and compliance, elevation in

diastolic pressures, left atrial and pulmonary venous hypertension, and pulmonary edema. Diastolic abnormalities can play a major role in the pathophysiology of heart failure, particularly in the presence of myocardial ischemia and hypertrophy.

Conventional treatment of systolic dysfunction includes the use of positive inotropic agents. Implicit in the use of these agents is the concept that inotropic stimulation, by enhancing the force and extent of contraction of functional myocytes, may improve cardiac function, symptoms of heart failure, and prolong life. Recently, however, several reports have challenged these traditional ideas, and stimulated considerable controversy. It has been shown that the longterm use of positive inotropic agents may be of no benefit, or even detrimental in patients with chronic heart failure. Studies suggesting that selected patients with severe left ventricular dysfunction may even benefit from treatment with some negative inotropic agents (beta blockers) have stimulated even greater debate.

The purpose of this brief article is to review the longterm effects of positive inotropic agents in chronic left ventricular failure. We will not review all aspects of therapy of heart failure, or the short-term effects of temporary inotropic support.

*From the Division of Cardiology, Department of Medicine, Carraway Methodist Medical Center and the Norwood Clinic, Birmingham, Alabama. Supported in part by the Kemp-Carraway Heart Institute, Birmingham, Alabama.

Address for reprints: Silvio E. Papapietro, M.D., Division of Cardiology, Carraway Methodist Medical Center, 1600 North 26th St., Birmingham, AL 35234.

Digitalis

Despite 200 years of use, the role of digitalis in the treatment of congestive heart failure in patients with sinus rhythm remains highly controversial. Digitalis inhibits membrane sodium-potassium ATPase and enhances calcium entry into the cell. They have a mild positive inotropic effect, and are of benefit in patients with heart failure and atrial fibrillation. In these patients, the salutary effects are well documented, and relate to a reduction in heart rate. There are no controlled studies, however, that convincingly demonstrate improvement in symptoms or survival in patients with heart failure and sinus rhythm treated with digitalis. In a recent search of the English literature from 1960-1982, Mulrow et al¹ found 16 articles that attempted to evaluate the effects of digitalis in patients with congestive heart failure and sinus rhythm. Only two double-blind, placebo controlled studies, provided clinically useful information. One study² showed that digoxin therapy could be withdrawn without detriment in elderly patients with stable congestive heart failure. The other study³ showed that patients with chronic heart failure and an S3 gallop benefited clinically from digoxin therapy. These authors concluded that virtually no definitive evidence exists showing the proper therapeutic role of digitalis for patients with heart failure and sinus rhythm. Concern has emerged about the use of digitalis in patients with a recent myocardial infarction. Several studies published since 1981 have demonstrated a higher mortality for patients treated with digitalis after an acute myocardial infarction, than those not receiving the drug.⁴⁻⁷ None of these studies were randomized, and it is not possible to determine if the higher mortality of the digitalis-treated patients was related to the drug, or other conditions that made these patients a higher risk subgroup. After reviewing four of these studies, Bigger et al⁸ concluded that in these post-infarction patients the risk associated with digitalis use could not be explained by baseline differences in groups.

To date, there is no convincing evidence that long-term use of digitalis in patients with chronic left ventricular dysfunction favorably influences survival. Furthermore, there is concern about an increased mortality associated with the use of digitalis in post infarction patients, although this issue remains unresolved.

Catecholamines

The beta receptor agonists dopamine and dobutamine have been available for several years. The intravenous administration of these agents can result in dramatic short-term hemodynamic effects, when given to patients with severe congestive heart failure.

Despite short-term hemodynamic improvement, a number of studies have challenged their longterm beneficial effect. The use of these agents is frequently

associated with a tachycardia, and the harmful effects of a chronic increase in heart rate in patients with ventricular dysfunction are well established. In addition, longterm treatment with a beta receptor agonist frequently leads to hemodynamic tolerance, probably related to a progressive decrease in the number of active beta receptors ("down regulation"), and a reduction in the effectiveness of the drug.

Of even greater concern that the short-lived hemodynamic effects and the development of tolerance, are the potentially hazardous effects of longterm beta adrenergic stimulation. Dawson reported a disturbing 32% mortality after three months in 63 patients treated with oral pirbuterol, a beta-2 agonist agent.⁹ In a recent multicenter trial designed to evaluate the effects of intermittent intravenous dobutamine in patients with congestive heart failure,¹⁰ the use of the drug was associated with increased exercise tolerance, but an alarming mortality of 48%, compared to 17% in the placebo treated group. These results prompted the premature termination of the study.

Almost simultaneously with these reports suggesting a pernicious effect of longterm beta stimulation, several groups of investigators have reported beneficial effects associated with longterm beta receptor blockade in selected patients with chronic left ventricular dysfunction. Following the initial studies in Goteborg, Sweden, by Waagstein et al showing improved ventricular function and survival in patients with dilated cardiomyopathy treated with metoprolol,^{11, 12} other groups of investigators have evaluated the longterm effects of beta blockade.¹³⁻¹⁶ Despite a wide-spread belief by the medical community that beta blockers are harmful to patients with heart failure, it has become apparent that a subpopulation of patients benefits considerably from this therapy, with improvement in function and survival. The mechanisms responsible for the favorable effects associated with beta blocking agents may include: (1) reduction in heart rate and contractility, with more energy becoming available for synthetic and reparative processes, (2) improved diastolic relaxation, filling and compliance, (3) inhibition of sympathetically mediated vasoconstriction via prostaglandins and renin, (4) protection against catecholamine-induced myocardial damage and necrosis, and (5) "up regulation" of beta receptors, with restoration of catecholamine responsiveness.

A number of large scale randomized trials have also shown that patients treated with beta blockers within one month after an acute myocardial infarction have approximately a 30% reduction in mortality when compared to those treated with placebo.¹⁷ Of interest is the observation that beta blockers with intrinsic sympathomimetic activity, like pindolol, appear not to share this beneficial effect.

There is now evidence that longterm treatment with beta adrenergic agonists does not prolong life, and may

be detrimental in patients with severe left ventricular dysfunction and heart failure. Conversely, in selected patients with left ventricular dysfunction, particularly post infarction, the longterm use of beta blockade may be associated with improved survival.

Phosphodiesterase Inhibitors

Amrinone, a phosphodiesterase inhibitor, recently became available for the treatment of patients with congestive failure and ventricular dysfunction. This agent inhibits phosphodiesterase, increases intracellular cyclic AMP, and has positive inotropic and vasodilator effects.

Several groups of investigators have demonstrated marked short-term hemodynamic effects associated with amrinone therapy in severe congestive heart failure. However, these studies have also shown significant deterioration in left ventricular function during amrinone therapy, suggesting accelerated progression of myocardial dysfunction.¹⁸ In a recent editorial,¹⁹ Franciosa concluded that amrinone appears to have no advantage over similar agents, may be more toxic, and found no reason to justify its use.

Discussion

It has become apparent that the longterm use of positive inotropic agents in patients with chronic left ventricular dysfunction does not prolong life or favorably influences the natural history of the disease. The use of these agents may even be associated with decreased survival rates.

The mechanisms underlying the unfavorable effects of longterm positive inotropic stimulation remain speculative. Almost 15 years ago, Katz postulated that the failing heart is energy-starved, and the impairment in contractility associated with ventricular dysfunction may represent a compensatory mechanism of myocardial cells to reduce energy utilization, and thereby preserve myocardial life.²⁰ Augmentation of contractility of digitalis, beta adrenergic agonists, or phosphodiesterase inhibitors, could result in temporary improvement in cardiac function, at the expense of increasing myocardial energy consumption, and acceleration of myocardial cell death. This sequence of events is particularly likely in ischemic ventricular dysfunction, in which the increase in oxygen demand associated with an increase in contractility may lead to further aggravation of myocardial ischemia. Positive inotropic agents also can precipitate or exacerbate ventricular tachyarrhythmias. Nearly all positive inotropic agents increase the amount of calcium in the cytosol during systole, and can produce delayed afterdepolarizations, which may play a critical role in the pathogenesis of arrhythmias. Beta receptor agonists may produce hypokalemia by increasing the transmembrane transport of extracellular potassium into the cells. Hypokalemia may represent an additional arrhythmogenic

factor, particularly in patients receiving concomitant therapy with digitalis. In the presence of hypertrophy and diastolic left ventricular dysfunction, the increased rate of energy utilization by the inotropically stimulated heart can exacerbate relaxation abnormalities, aggravate diastolic dysfunction, and further increase left ventricular diastolic and pulmonary venous pressure.²¹ As postulated by Katz, the impairment in contractile state of the abnormal left ventricle may represent an adaptative mechanism to reduce the rate of energy expenditure, and preserve myocardial life. Using positive inotropic agents to stimulate a "sick and dying heart" may be as irrational as "whipping a dying horse." It is likely the horse will run faster for a shorter distance, before dying prematurely.

Some time-honored ideas that have guided the treatment of chronic heart failure are undergoing drastic revision. Basic concepts have been challenged, and therapeutic options that were considered contraindicated (use of beta blockers) have proved beneficial in selected patients. Contrary to the effects of longterm positive inotropic stimulation, reduction in cardiac load with vasodilators has been shown to improve ventricular function, reduce myocardial energy requirements, and improve survival.^{22, 23}

In the practice of medicine, rational thinking carries an inherent risk. What may appear rational today, may become less rational or even irrational under the light of new scientific information tomorrow. It is smarter (and safer) to treat based on evidence rather than concepts, regardless of how irresistibly appealing these concepts may appear.

After 200 years of "whipping" failing ventricles, it may be time for reflection. □

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Better Control of Diabetes Through Exercise (Personal Experience)

Jill F. Bresman, B.S.
Bernard H. Eichold, M.D.*

In 1975, Dr. Irving Dardik, a cardiovascular surgeon, and senior physician for the U.S. Olympic Team, with the help of Michael O'Shea, owner of the Sports Training Institute in New York City, initiated a Nautilus training program for several diabetic adolescents.

I was seventeen at the time, and had diabetes for nine years. Exercise quickly became a very important part of my life. I immediately noticed improvement in the way I felt. At the risk of sounding like a fanatic, I had far greater energy, required less sleep, and had an overall sense of physical and emotional well-being. In addition, my diabetes control improved dramatically. By stabilizing my body weight, my insulin requirement decreased, and my blood sugars and glycosylated hemoglobin content (a measure of long-term blood-glucose control) improved.

Almost 10 years later, I am still exercising. As a recreational therapist at the Diabetic Treatment Unit of the New England Deaconess Hospital at the Joslin Diabetes Center, I feel that the regimen of regular

aerobic exercise should be emphasized as an essential component of blood-glucose control and cardiovascular fitness to benefit others with diabetes like myself.

Most diabetologists agree that the three essential components to diabetes management are: diet, exercise and hypoglycemic (glucose lowering) medications such as insulin or oral agents. Most people with diabetes find that taking their prescribed medications is very easy. Following a carefully designed meal plan however, is more difficult and requires extraordinary self-discipline. A majority of people have time to exercise daily, but they are simply not motivated enough to initiate such a program. Trying to motivate people with diabetes to exercise can be a very frustrating experience, especially to a person like myself, a type I diabetic who is dedicated to exercise and can personally attest to its benefits.

In this article, my personal experiences as a recreational therapist at the Diabetes Treatment Unit are presented not to discourage others from establishing exercise programs, but to outline some of the potential difficulties and their solutions so that others will hopefully be successful.

* Diabetes Treatment Unit of the New England Deaconess Hospital at the Joslin Diabetes Center, Boston, Massachusetts 02215

Origin of Program

A pilot exercise study was designed. While all patients entering the Diabetes Treatment Unit of the New England Deaconess Hospital at the Joslin Diabetes Center are offered an individualized exercise program, only those patients specifically requesting such a program were considered in this study. Prior to entering the study, patients received medical clearance from their doctors. Each patient was then seen on an individual basis to discuss a personalized exercise program. An exercise history was taken. A few of the factors considered included: (1) prior exercise experience, (2) duration of diabetes, (3) exercise goals, (4) exercise preference, (5) time limitations, and (6) available resources. Each program was tailored to each patient's individual needs.

Patients were educated with respect to the essential components of an exercise program with special emphasis on diabetes management and cardiovascular fitness. These components include: (1) frequency of exercise (how often), (2) duration of exercise (how long), and (3) intensity of exercise (how hard).

Patients were recommended to exercise four times each week, or every other day. It was emphasized that each person has a different starting point, and they should therefore begin by exercising until they felt tired, and then increase the duration of their activity in 10% increments each week to a maximum duration of twenty to thirty minutes. To evaluate how hard to exercise, patients were taught how to estimate their pulse, and were given a target heart rate to strive for based upon their age, exercising between 65%-75% of their maximum potential (Table 1).

Some of the activities suggested included walking, jogging, bicycling, swimming and in some cases an aerobic weight lifting program. Patients were also given helpful diabetic management hints which included insulin and/or diet adjustment, blood glucose monitoring, checking for ketones, choosing an injection site, and the lag effect of exercise (Table 2). Each patient was given an exercise chart to keep records of their progress. This chart not only served as a motivational tool, but also allowed patients to keep track of their increasing exercise tolerance (heart rate, duration, intensity), and insulin reactions. After discharge, each patient was encouraged to keep us informed of their progress by sending back their exercise charts one month after beginning their program. A standardized questionnaire was sent to each patient following their discharge.

Outcome

From August 16, 1982 to September 22, 1983, seventy patients admitted to the Diabetes Treatment Unit received individualized exercise programs. Patients ranged from seventeen to sixty years of age.

Of the seventy patients who received an individualized program, only eighteen patients (26%) responded one month after discharge, 17 (24%) of which were overwhelmingly positive. Patients reported weight loss, increased energy, improved mental status, and improved blood glucose control.

Up to 13 months after discharge, questionnaires were sent to each of the seventy patients resulted in twenty-five responses. Of these responses, fifteen reported

continued on page 36

Table 1
Exercise Heart Rate By Age

Age	Predicted Maximal Heart Rate	90% max	85% max	80% max	75% max	70% max	65% max	60% max
15	193	174	164	154	145	135	125	116
20	191	172	162	153	143	134	124	115
25	189	170	161	151	142	133	123	113
30	186	167	158	149	140	130	121	111
35	184	166	156	147	138	129	120	110
40	182	164	155	146	137	127	118	109
45	180	162	153	144	135	126	117	108
50	178	160	151	142	134	125	116	107
55	175	158	149	140	131	123	114	105
60	173	156	147	138	130	121	112	104
65	171	154	145	137	128	120	111	103

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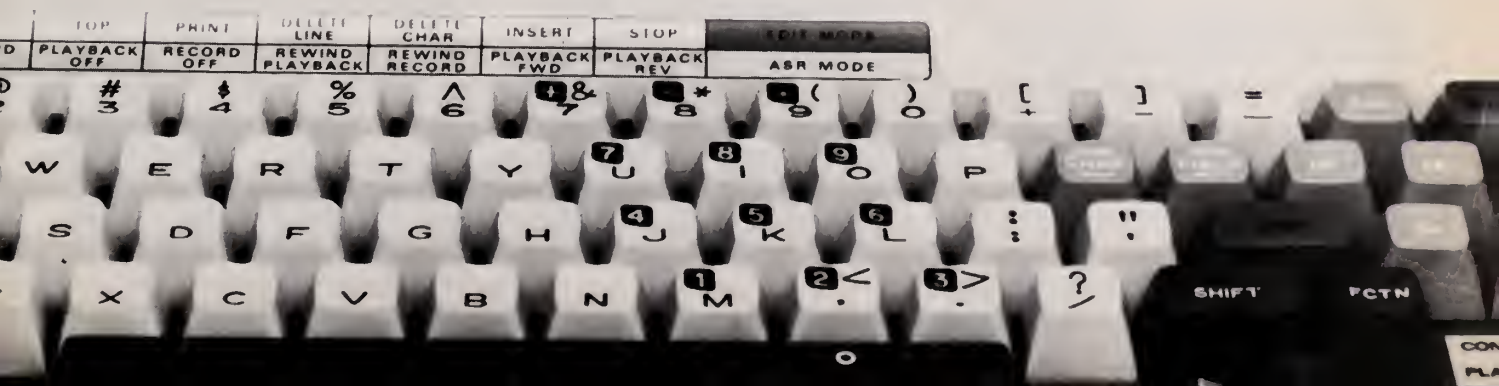


Table 2
Diabetes Management Hints for Exercise

-
1. Obtain medical clearance.
 2. Adjust insulin or meal plan according to blood and urine glucose levels.
 3. Lag effect: There is a 24 hour lag effect after exercise stops. Therefore, you will notice positive effects on your blood sugars the day after you exercise.
 4. Injection site: Never inject the exercising area of the body. Insulin is absorbed twice as fast.
 5. Ketones: Never exercise if you are spilling high sugars plus ketones. Blood sugars will increase in response to exercise.
 6. Use proper equipment.
 7. Stretch, warm up and cool down to prevent injuries.
-

that they were still exercising, and enjoying the benefits described above. Of the fifteen positive responses, eleven exercised three to four times each week, and four exercised five to seven times each week. Two patients exercised less than fifteen minutes, five patients exercised from fifteen to thirty minutes, five patients exercised from thirty to sixty minutes, and three patients exercised greater than sixty minutes each day. Ten of the twenty-five patients who answered the questionnaire responded that they were not currently engaged in an exercise program. Four patients discontinued their programs within two months of discharge, while the remaining six patients discontinued their programs within four to nine months of discharge. Reasons given for non-compliance included time constraints, loss of motivation, and injury.

Conclusion

There was a great deal of interest and enthusiasm when patients began their individualized exercise program which was initiated in an in-patient setting. Over-

all compliance was fair: 26% were still exercising one month after discharge, while 21% complied after as great as thirteen months after discharge. Long-term compliers reported weight loss, better control of their diabetes, increased energy, and an overall improved quality of life.

Many reasons were given for discontinuing the program. Lack of motivation due to little peer support was the primary cause for non-compliance. Long-term compliance can be significantly increased by the organization of peer-support groups, similar in structure and function to Weight Watchers, or Alcoholics Anonymous. These peer-support groups will serve to maintain the motivational levels of its members, and to foster individual and group activities for the improved management of diabetes.

Finally, injuries can be prevented by being sure to stretch out and warm up prior to exercising, and to be sure to include a cool-down period following the exercise period. Careful attention to the purchase of the correct equipment (i.e. running shoes, exercise bike, etc.) can also aid in preventing injuries. ◻

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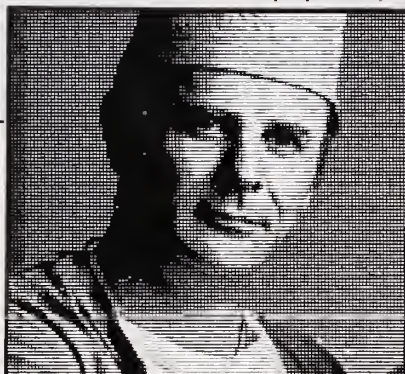
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CLINICAL PHARMACOLOGY. INDERAL is a nonselective, beta-adrenergic receptor-blocking agent possessing no other autonomic nervous system activity. It specifically competes with beta-adrenergic receptor-stimulating agents for available receptor sites. When access to beta-receptor sites is blocked by INDERAL, the chronotropic, inotropic, and vasodilator responses to beta-adrenergic stimulation are decreased proportionately.

INDERAL LA Capsules (60, 80, 120, and 160 mg) release propranolol HCl at a controlled and predictable rate. Peak blood levels following dosing with INDERAL LA occur at about 6 hours and the apparent plasma half-life is about 10 hours. When measured at steady state over a 24-hour period the areas under the propranolol plasma concentration-time curve (AUCs) for the capsules are approximately 60% to 65% of the AUCs for a comparable divided daily dose of INDERAL Tablets. The lower AUCs for the capsules are due to greater hepatic metabolism of propranolol, resulting from the slower rate of absorption of propranolol. Over a twenty-four (24) hour period, blood levels are fairly constant for about twelve (12) hours then decline exponentially.

INDERAL LA should not be considered a simple mg-for-mg substitute for conventional propranolol and the blood levels achieved do not match (are lower than) those of two to four times daily dosing with the same dose. When changing to INDERAL LA from conventional propranolol, a possible need for retitration upwards should be considered especially to maintain effectiveness at the end of the dosing interval. In most clinical settings, however, such as hypertension or angina where there is little correlation between plasma levels and clinical effect, INDERAL LA has been therapeutically equivalent to the same mg dose of conventional INDERAL as assessed by 24-hour effects on blood pressure and on 24-hour exercise responses of heart rate, systolic pressure and rate pressure product. INDERAL LA can provide effective beta blockade for a 24-hour period.

INDICATIONS AND USAGE. Hypertension: INDERAL LA is indicated in the management of hypertension; it may be used alone or used in combination with other antihypertensive agents, particularly a thiazide diuretic. INDERAL LA is not indicated in the management of hypertensive emergencies.

Angina Pectoris Due to Coronary Atherosclerosis: INDERAL LA is indicated for the long-term management of patients with angina pectoris.

Migraine: INDERAL LA is indicated for the prophylaxis of common migraine headache. The efficacy of propranolol in the treatment of a migraine attack that has started has not been established and propranolol is not indicated for such use.

Hypertrophic Subaortic Stenosis: INDERAL LA is useful in the management of hypertrophic subaortic stenosis, especially for treatment of exertional or other stress-induced angina, palpitations, and syncope. INDERAL LA also improves exercise performance. The effectiveness of propranolol hydrochloride in this disease appears to be due to a reduction of the elevated outflow pressure gradient which is exacerbated by beta-receptor stimulation. Clinical improvement may be temporary.

CONTRAINDICATIONS. INDERAL is contraindicated in 1) cardiogenic shock, 2) sinus bradycardia and greater than first-degree block, 3) bronchial asthma, 4) congestive heart failure (see WARNINGS) unless the failure is secondary to a tachyarrhythmia treatable with INDERAL.

WARNINGS. CARDIAC FAILURE. Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive heart failure, and its inhibition by beta blockade may precipitate more severe failure. Although beta blockers should be avoided in overt congestive heart failure, if necessary, they can be used with close follow-up in patients with a history of failure who are well compensated and are receiving digitalis and diuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitalis on heart muscle.

IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta blockers can, in some cases, lead to cardiac failure. Therefore, at the first sign or symptom of heart failure, the patient should be digitalized and/or treated with diuretics, and the response observed closely, or INDERAL should be discontinued (gradually, if possible).

IN PATIENTS WITH ANGINA PECTORIS, there have been reports of exacerbation of angina and in some cases, myocardial infarction, following abrupt discontinuance of INDERAL therapy. Therefore, when discontinuance of INDERAL is planned, the dosage should be gradually reduced over at least a few weeks, and the patient should be cautioned against interruption or cessation of therapy without the physician's advice. If INDERAL therapy is interrupted and exacerbation of angina occurs, it usually is advisable to reinstitute INDERAL therapy and take other measures appropriate for the management of unstable angina pectoris. Since coronary artery disease may be unrecognized, it may be prudent to follow the above advice in patients considered at risk of having occult atherosclerotic heart disease who are given propranolol for other indications.

Nonallergic Bronchospasm (eg, chronic bronchitis, emphysema) - PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD IN GENERAL NOT RECEIVE BETA BLOCKERS. INDERAL should be administered with caution since it may block bronchodilation produced by endogenous and exogenous catecholamine stimulation of beta receptors.

MAJOR SURGERY. The necessity or desirability of withdrawal of beta-blocking therapy prior to major surgery is controversial. It should be noted, however, that the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.

INDERAL (propranolol HCl), like other beta blockers, is a competitive inhibitor of beta-receptor agonists and its effects can be reversed by administration of such agents, eg, dobutamine or isoproterenol. However, such patients may be subject to protracted severe hypotension. Difficulty in starting and maintaining the heartbeat has also been reported with beta blockers.

DIABETES AND HYPOGLYCEMIA. Beta blockers should be used with caution in diabetic patients if a beta-blocking agent is required. Beta blockers may mask tachycardia occurring with hypoglycemia, but other manifestations such as dizziness and sweating may not be significantly affected. Following insulin-induced hypoglycemia, propranolol may cause a delay in the recovery of blood glucose to normal levels.

THYROTOXICOSIS. Beta blockade may mask certain clinical signs of hyperthyroidism. Therefore, abrupt withdrawal of propranolol may be followed by an exacerbation of symptoms of hyperthyroidism, including thyroid storm. Propranolol may change thyroid function tests, increasing T₄ and reverse T₃, and decreasing T₃.

IN PATIENTS WITH WOLFF-PARKINSON-WHITE SYNDROME, several cases have been reported in which, after propranolol, the tachycardia was replaced by a severe bradycardia requiring a demand pacemaker. In one case, this resulted after an initial dose of 5 mg propranolol.

PRECAUTIONS. GENERAL. Propranolol should be used with caution in patients with impaired hepatic or renal function. INDERAL (propranolol HCl) is not indicated for the treatment of hypertensive emergencies.

Beta-adrenoreceptor blockade can cause reduction of intraocular pressure. Patients should

be told that INDERAL may interfere with the glaucoma screening test. Withdrawal may lead to a return of increased intraocular pressure.

CLINICAL LABORATORY TESTS. Elevated blood urea levels in patients with severe heart disease, elevated serum transaminase, alkaline phosphatase, lactate dehydrogenase.

DRUG INTERACTIONS. Patients receiving catecholamine-depleting drugs such as reserpine should be closely observed if INDERAL is administered. The added catecholamine-blocking action may produce an excessive reduction of resting sympathetic nervous activity which may result in hypotension, marked bradycardia, vertigo, syncopal attacks, or orthostatic hypotension.

Caution should be exercised when patients receiving a beta blocker are administered a calcium-channel-blocking drug, especially intravenous verapamil, for both agents may depress myocardial contractility or atrioventricular conduction. On rare occasions, the concomitant intravenous use of a beta blocker and verapamil has resulted in serious adverse reactions, especially in patients with severe cardiomyopathy, congestive heart failure or recent myocardial infarction.

Aluminum hydroxide gel greatly reduces intestinal absorption of propranolol.

Ethanol slows the rate of absorption of propranolol.

Phenyltoin, phenobarbital, and rifampin accelerate propranolol clearance.

Chlorpromazine, when used concomitantly with propranolol, results in increased plasma levels of both drugs.

Antipyrine and lidocaine have reduced clearance when used concomitantly with propranolol.

Thyroxine may result in a lower than expected T₃ concentration when used concomitantly with propranolol.

Cimetidine decreases the hepatic metabolism of propranolol, delaying elimination and increasing blood levels.

Theophylline clearance is reduced when used concomitantly with propranolol.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY. Long-term studies in animals have been conducted to evaluate toxic effects and carcinogenic potential. In 18-month studies in both rats and mice, employing doses up to 150 mg/kg day, there was no evidence of significant drug-induced toxicity. There were no drug-related tumorigenic effects at any of the dosage levels. Reproductive studies in animals did not show any impairment of fertility that was attributable to the drug.

PREGNANCY. Pregnancy Category C. INDERAL has been shown to be embryotoxic in animal studies at doses about 10 times greater than the maximum recommended human dose.

There are no adequate and well-controlled studies in pregnant women. INDERAL should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

NURSING MOTHERS. INDERAL is excreted in human milk. Caution should be exercised when INDERAL (propranolol HCl) is administered to a nursing woman.

PEDIATRIC USE. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS. Most adverse effects have been mild and transient and have rarely required the withdrawal of therapy.

Cardiovascular. Bradycardia, congestive heart failure, intensification of AV block, hypotension, paresthesia of hands, thrombocytopenic purpura, arterial insufficiency, usually of the Raynaud type.

Central Nervous System. Light-headedness, mental depression manifested by insomnia, lassitude, weakness, fatigue, reversible mental depression progressing to cataplexy, visual disturbances, hallucinations, vivid dreams, an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics. For immediate formulations, fatigue, lethargy and vivid dreams appear dose related.

Gastrointestinal. Nausea, vomiting, epigastric distress, abdominal cramping, diarrhea, constipation, mesenteric arterial thrombosis, ischemic colitis.

Allergic. Pharyngitis and agranulocytosis, erythematous rash, fever combined with aching and sore throat, laryngospasm and respiratory distress.

Respiratory. Bronchospasm.

Hematologic. Agranulocytosis, nonthrombocytopenic purpura, thrombocytopenic purpura.

Auto-Immune. In extremely rare instances, systemic lupus erythematosus has been reported.

Miscellaneous. Alopecia, LE-like reactions, psoriasiform rashes, dry eyes, male impotence, and Peyronie's disease have been reported rarely. Oculomucocutaneous reactions involving the skin, serous membranes and conjunctivae reported for a beta blocker (practolol) have not been associated with propranolol.

DOSEAGE AND ADMINISTRATION. INDERAL LA provides propranolol hydrochloride in a sustained-release capsule for administration once daily. If patients are switched from INDERAL Tablets to INDERAL LA Capsules, care should be taken to assure that the desired therapeutic effect is maintained. INDERAL LA should not be considered a simple mg-for-mg substitute for INDERAL. INDERAL LA has different kinetics and produces lower blood levels. Retitration may be necessary, especially to maintain effectiveness at the end of the 24-hour dosing interval.

HYPERTENSION—Dosage must be individualized. The usual initial dosage is 80 mg INDERAL LA once daily, whether used alone or added to a diuretic. The dosage may be increased to 120 mg once daily or higher until adequate blood-pressure control is achieved. The usual maintenance dosage is 120 to 160 mg once daily. In some instances a dosage of 640 mg may be required. The time needed for full hypertensive response to a given dosage is variable and may range from a few days to several weeks.

ANGINA PECTORIS—Dosage must be individualized. Starting with 80 mg INDERAL LA once daily, dosage should be gradually increased at three- to seven-day intervals until optimal response is obtained. Although individual patients may respond at any dosage level, the average optimal dosage appears to be 160 mg once daily. In angina pectoris, the value and safety of dosage exceeding 320 mg per day have not been established.

If treatment is to be discontinued, reduce dosage gradually over a period of a few weeks (see WARNINGS).

MIGRAINE—Dosage must be individualized. The initial oral dose is 80 mg INDERAL LA once daily. The usual effective dose range is 160-240 mg once daily. The dosage may be increased gradually to achieve optimal migraine prophylaxis. If a satisfactory response is not obtained within four to six weeks after reaching the maximal dose, INDERAL LA therapy should be discontinued. It may be advisable to withdraw the drug gradually over a period of several weeks.

HYPERTROPHIC SUBAORTIC STENOSIS—80-160 mg INDERAL LA once daily.

PEDIATRIC DOSAGE—At this time the data on the use of the drug in this age group are too limited to permit adequate directions for use.

*The appearance of these capsules is a registered trademark of Ayerst Laboratories.

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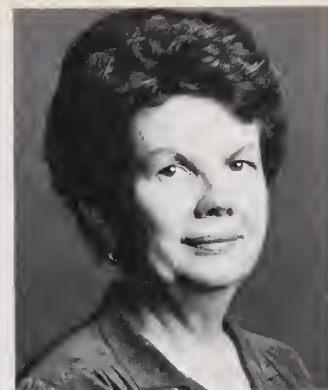
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*Mrs. Lamar Thomas
A-MASA President*

Coping with Alzheimer's Disease

Alzheimer's Disease is a progressive neurological disorder that causes victims to lose memory and the ability to think logically and care for themselves. Some 3 million persons have Alzheimer's, which strikes an estimated 5% to 7% of persons older than age 65 and an estimated one in five of those older than 80 years.

The annual cost of caring for patients with Alzheimer's is \$40 billion to \$80 billion. Victims of the disorder often require years of custodial care that is not covered by medicare; the emotional and financial costs of that care can be devastating to their families. The number of people 65 and older, now at 28 million, is growing twice as fast as the population as a whole; the number 85 and older is growing more than five times faster.

The sobering flip side of the increased longevity and prosperity of older people is the chronic illness and disability that plague an estimated one in five elderly. Cancer, diabetes, Alzheimer's disease, osteoporosis, arthritis, and cardiovascular disease are among the crippling conditions that hit the elderly hardest.¹

At first the symptoms of Alzheimer's are almost imperceptible but progressively become more pronounced. Family members have used the following

phrases to describe the behavior of victims of Alzheimer's: "irritable, anxious, distressed, delusional, afraid to move from one setting to another," "hostile, aggressive behavior and difficulty communicating clearly," "wouldn't socialize," "did nothing but sleep in front of TV," and "sleepless nights, disturbing others."

At this time medical science has only been able to determine that the symptoms occur as a result of deficiencies in certain chemicals and enzymes known as neurotransmitters. Whether these deficiencies are caused by a slow-acting virus, a genetic factor, or some other agent is not yet known.²

Scientists have suggested possible links between head injuries and Alzheimer's disease. Aluminum, also, has been frequently blamed as the cause though science has no proof to that effect. Recent research reported in the JCMA suggests that a prenatal infection associated with Chromosome 21 might be the culprit.

Possible experimental treatment proposed as a result of research include the use of tetrahydroaminoachrine, or THA. While reversing the symptoms related to memory deficits for a while, victims will probably reach a point when they are no longer helped by the drug.

Another proposed treatment is fetal brain tissue transplantation. While proposing far reaching therapeutic promise it also poses technical as well as ethical problems.

Though little is known to date concerning causes or treatments of Alzheimer's disease those who provide care for these victims have begun to establish appropriate custodial care for them. Eighty percent of Alzheimer's victims are cared for in part at home by family members.

Nursing homes are an option when the family can't cope. Some nursing homes will not accept Alzheimer's patients at all because of the disruptive behavior and safety risk. Many patients have been restrained or sedated while in nursing homes.

There are alternatives to these situations.

Day care centers are an attractive alternative to nursing homes and home health care. They offer both family respite and patient companionship.

There are only 20 day care centers in the country specifically for Alzheimer's patients. Alzheimer's Family Care Center is Chicago's first and opened June 1987. The Chicago Center does not take a "baby-sitter" attitude. The staff tries to engage its clients any way they can — preferably with memory games, physical exercises, music therapy and conversation. They do not need nursing care as much as companionship and attention and someone who knows how to deal with erratic behavior.³

Another alternative is an Alzheimer's unit in an existing nursing home. The Good Shepherd program located at Willow Wood Home in New Orleans is a good example. In describing the ten women who compose the unit, the director says, "... formerly productive women, active in social and civic activities. Now in their late 60's or older, these women have reverted to childlike ways and must be constantly watched for their own safety. They are victims of Alzheimer's Disease, a debilitating condition that sometimes wipes away all traces of one's personality."

"There are no known cures for the affliction, and very little information about what to do for the victims. Most of them wind up in nursing homes, to spend the remainder of their days wandering about in a confused and agitated state."⁴

A unique care facility is Sansing Home in Pickens County. It is a domiciliary committed to providing

quality care for their 15 residents including four with the symptoms of Alzheimer's. Located in a peaceful, serene farm setting, Sansing is only minutes from medical care in Carrollton, Alabama. Florea Sansing exhibits the patience and understanding of the elderly necessary to deal with sometimes scared, agitated, unwilling or suspicious patients.

In addition to planned activities such as simple crafts, parties, singing and outings, Alzheimer's residents are encouraged to help perform once familiar tasks, such as folding clothes, shelling peas or gardening. Local ministers come for weekly worship services and church groups invite them for occasional activities. Local Mennonite families usually spend Sunday afternoons visiting.

No matter where the care is given, the key to caring for Alzheimer's victims is constantly giving them positive reinforcement and providing support services for the patients' families.

One of the prime responsibilities of physicians caring for Alzheimer's patients is to give a reasonably accurate diagnosis and urge the family to take quick action. Long range planning should be undertaken in terms of financial and legal aspects. Patients can be treated for depression, agitation and sleep disorders but families need guidance through the legal, financial, and insurance maze. When doctors take on an Alzheimer's patient, they are taking on the responsibility of providing continual support to the patient and to the family. □

Carole

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4. Perry, James A.: "Help for Alzheimer's Victims." The Times-Picayune, E-3, Feb. 25, 1987.

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- Only 1/3 the dropout rate due to side effects of amitriptyline alone, although the incidence of side effects is similar¹

Caution patients about the combined effects of Limbitrol with alcohol or other CNS depressants and about activities requiring complete mental alertness, such as operating machinery or driving a car. In general, limit dosage to the lowest effective amount in elderly patients.

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References: 1. Feighner JP, et al. *Psychopharmacology* 61:217-225, Mar 22, 1979. 2. Data on file, Hoffmann-La Roche Inc., Nutley, NJ

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Tranquiliizer—Antidepressant

Before prescribing, please consult complete product information, a summary of which follows:

Indications: Relief of moderate to severe depression associated with moderate to severe anxiety

Contraindications: Known hypersensitivity to benzodiazepines or tricyclic antidepressants. Do not use with monoamine oxidase (MAO) inhibitors or within 14 days following discontinuation of MAO inhibitors since hyperpyretic crises, severe convulsions and deaths have occurred with concomitant use, then initiate cautiously, gradually increasing dosage until optimal response is achieved. Contraindicated during acute recovery phase following myocardial infarction.

Warnings: Use with great care in patients with history of urinary retention or angle-closure glaucoma. Severe constipation may occur in patients taking tricyclic antidepressants and anticholinergic-type drugs. Closely supervise cardiovascular patients (Arrhythmias, sinus tachycardia and prolongation of conduction time reported with use of tricyclic antidepressants, especially high doses. Myocardial infarction and stroke reported with use of this class of drugs.) Caution patients about possible combined effects with alcohol and other CNS depressants and against hazardous occupations requiring complete mental alertness (e.g., operating machinery, driving).

Usage in Pregnancy: Use of minor tranquilizers during the first trimester should almost always be avoided because of increased risk of congenital malformations as suggested in several studies. Consider possibility of pregnancy when instituting therapy; advise patients to discuss therapy if they intend to or do become pregnant.

Since physical and psychological dependence to chlordiazepoxide have been reported rarely, use caution in administering Limbitrol to addiction-prone individuals or those who might increase dosage, withdrawal symptoms following discontinuation of either component alone have been reported (nausea, headache and malaise for amitriptyline, symptoms [including convulsions] similar to those of barbiturate withdrawal for chlordiazepoxide).

Precautions: Use with caution in patients with a history of seizures, in hyperthyroid patients or those on thyroid medication, and in patients with impaired renal or hepatic function. Because of the possibility of suicide in depressed patients, do not permit easy access to large quantities in these patients. Periodic liver function tests and blood counts are recommended during prolonged treatment. Amitriptyline component may block action of guanethidine or similar antihypertensives. When tricyclic antidepressants are used concomitantly with cimetidine (Tagamet), clinically significant effects have been reported involving delayed elimination and increasing steady state concentrations of the tricyclic drugs. Concomitant use of Limbitrol with other psychotropic drugs has not been evaluated, sedative effects may be additive. Discontinue several days before surgery. Limit concomitant administration of ECT to essential treatment. See Warnings for precautions about pregnancy. Limbitrol should not be taken during the nursing period. Not recommended in children under 12. In the elderly and debilitated, limit to smallest effective dosage to preclude ataxia, oversedation, confusion or anticholinergic effects.

Adverse Reactions: Most frequently reported are those associated with either component alone: drowsiness, dry mouth, constipation, blurred vision, dizziness and bloating. Less frequently occurring

reactions include vivid dreams, impotence, tremor, confusion and nasal congestion. Many depressive symptoms including anorexia, fatigue, weakness, restlessness and lethargy have been reported as side effects of both Limbitrol and amitriptyline. Granulocytopenia, jaundice and hepatic dysfunction have been observed rarely.

The following list includes adverse reactions not reported with Limbitrol but requiring consideration because they have been reported with one or both components or closely related drugs.

Cardiovascular: Hypotension, hypertension, tachycardia, palpitations, myocardial infarction, arrhythmias, heart block, stroke.

Psychiatric: Euphoria, apprehension, poor concentration, delusions, hallucinations, hypomania and increased or decreased libido.

Neurologic: Incoordination, ataxia, numbness, tingling and paresthesias at the extremities, extrapyramidal symptoms, syncope, changes in EEG patterns.

Anticholinergic: Disturbance of accommodation, paralytic ileus, urinary retention, dilatation of urinary tract.

Allergic: Skin rash, urticaria, photosensitization, edema of face and tongue, pruritus.

Hematologic: Bone marrow depression including agranulocytosis, eosinophilia, purpura, thrombocytopenia.

Gastrointestinal: Nausea, epigastric distress, vomiting, anorexia, stomatitis, peculiar taste, diarrhea, black tongue.

Endocrine: Testicular swelling and gynecomastia in the male, breast enlargement, galactorrhea and minor menstrual irregularities in the female, elevation and lowering of blood sugar levels, and syndrome of inappropriate ADH (antidiuretic hormone) secretion.

Other: Headache, weight gain or loss, increased perspiration, urinary frequency, mydriasis, jaundice, alopecia, parotid swelling.

Overdosage: Immediately hospitalize patient suspected of having taken an overdose. Treatment is symptomatic and supportive. IV administration of 1 to 3 mg physostigmine salicylate has been reported to reverse the symptoms of amitriptyline poisoning. See complete product information for manifestation and treatment.

Dosage: Individualize according to symptom severity and patient response. Reduce to smallest effective dosage when satisfactory response is obtained. Larger portion of daily dose may be taken at bedtime. Single h.s. dose may suffice for some patients. Lower dosages are recommended for the elderly. Limbitrol DS (double strength) Tablets, initial dosage of three or four tablets daily in divided doses, increased up to six tablets or decreased to two tablets daily as required. Limbitrol Tablets, initial dosage of three or four tablets daily in divided doses, for patients who do not tolerate higher doses.

How Supplied: Double strength (DS) Tablets, white, film-coated, each containing 10 mg chlordiazepoxide and 25 mg amitriptyline (as the hydrochloride salt), and Tablets, blue, film-coated, each containing 5 mg chlordiazepoxide and 12.5 mg amitriptyline (as the hydrochloride salt). Available in bottles of 100 and 500, Tel-E-Dose[®] packages of 100, Prescription Paks of 50.



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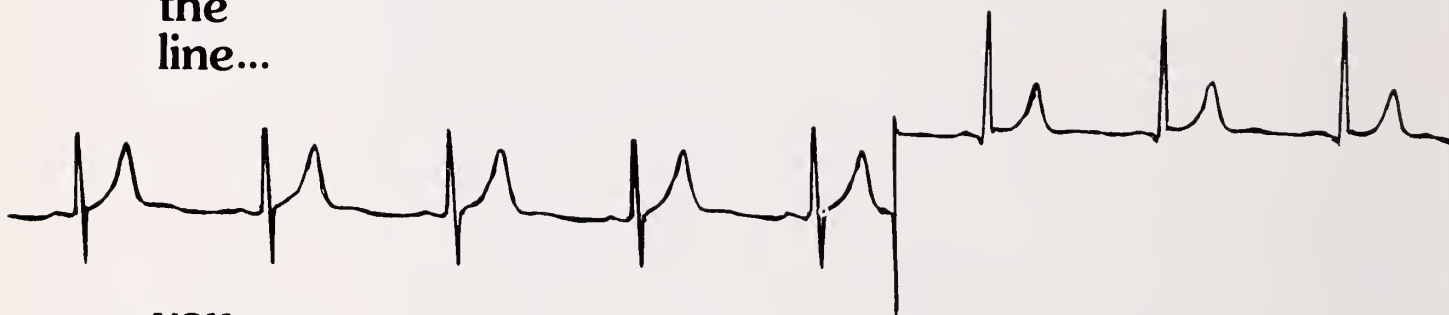
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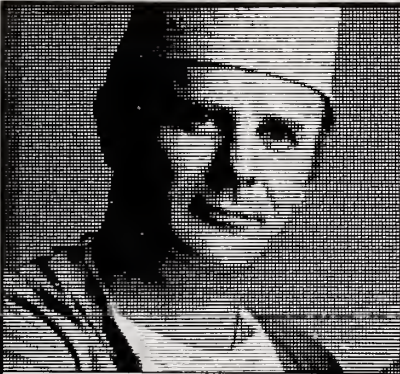
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The Cover

Many physicians have suggested union organization is the magic bullet for practitioners beset by the thumbscrew of third-party payors. The answer to the question on the cover is: Yes and no, mainly no. See Dr. Grote's presidential column, Pg. 8.

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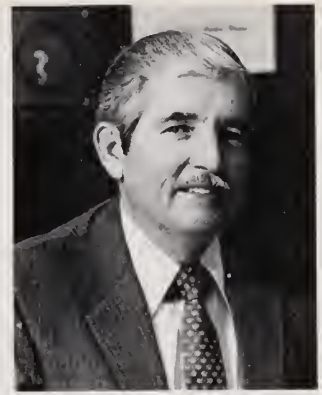
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S. Lon Conner
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What Is Medical Necessity?

Wherever the art of medicine is loved, there also is the love of humanity.

Hippocrates, Aphorisms, c. 400 B.C.

I read the above for the first time recently. I couldn't get it out of my mind. The nobility of the thought contrasts sharply with all the current attempts to K-Mart medicine. Particularly did it contrast with the direction I think I see federal medicine headed. A case in point:

A physician in rural Alabama was recently directed to refund \$20 to a Medicare patient whose painful bursitis he had relieved with cortisone. Under the new order imposed by Washington, the cortisone was decreed to be "medically unnecessary" by the fiscal intermediary.

I am sure many of you have Medicare horror stories that would eclipse this one. But sometimes what seems a relatively minor event is useful in studying the larger implications of an emerging concept, trend or dogma — in this case the federal concept of medical necessity.

Was the bursitis life-threatening? No. Would the treatment cure the patient? No. Then it follows that what would appear to this layman to be an entirely appropriate treatment of choice was not medically necessary by the cold algorithms of cookbook review.

Much of classic medicine, and indeed of recent Medicare expense, has been directed at enhancing the well-being and happiness of older Americans. But if the cortisone case is any kind of touchstone, I can only view with alarm what lies in store for the future.

One of the splendid accomplishments of Medicare has been providing the wherewithal for vision-impaired citizens to have cataract surgery, for example. Because of this highly developed procedure, uncounted thousands are now seeing what they could have only made out through a purblind veil. But where is the medical necessity in assisting retired Americans to live normal and rewarding years reading, sewing, watching television, savoring sunsets, witnessing the growth of their grandchildren? Is sight medically necessary?

For that matter, what is medically necessary? Is it limited to heroic efforts to forestall death, or does medicine have anything to do with enhancing the quality of life for Americans? Are we approaching the point when the feds will say the surgery to extirpate cancer is authorized but palliative surgery to relieve the pain and suffering of cancer is taboo because quality of life is a luxury outside the responsibility of federal medicine? The same would apply to many other procedures, including hip replacement.

I think I see an emerging definition of medical necessity that is truly frightening. If the test is to be whether the patient would have died had the treatment been withheld, dozens of therapies and procedures could be disallowed in *en masse*, at considerable saving, and that may eventuate very soon.

I like to believe I can look at all sides to any question. I believe I understand what HCFA's predicament is, in general terms at least: it is the instrument of the implied (but never articulated) will of Congress to ration care and to fit expenditures to available resources. I know also that Congress is strapped for revenue. Even so, HCFA is thus charged with the execution of an inherently dishonest public policy, one that imposes rationing of resources while vehemently denying that rationing is going on.

Elected officials cannot, or will not, confess what they are doing. That was apparent in their design of the automatic trigger for the Gramm-Rudman law. To escape direct accountability at the polls, Congress adopted the ingenious expediency of a guillotine programmed to drop when the trigger-point was reached, as if untouched by human hands. Thus congressmen could deny responsibility to constituents enraged because their favorite program had been cut. The law did it, not them.

Social Security and its attachments are sacred cows in Washington. Even President Reagan, who does not often blink in eyeball-to-eyeball showdowns, has accepted this too. During the week of the great stock-market meltdown, when congressional leaders were clamoring for an economic summit conference on domestic policy, the President acquiesced to the demands. He would put everything on the table, he said, "everything but Social Security."

I am not questioning his making Social Security sacrosanct. Perhaps it should be. What I do question is moral necessity of making "medical necessity" the great cop-out for rationing scarce resources, and then blaming doctors for whatever shortfalls remain.


How long are Americans to continue swallowing the enormous fiction that care is not rationed? And how long will Americans permit Congress to avoid funding Medicare adequately and passing the buck for the inevitable failure?

One reason that Washington cannot admit to the near-collapse of the system is that it would then be admitting that the truth of what American physicians warned Congress before Medicare was enacted: that it was far too expansive in its promises to survive economically.

The bureaucrats are reluctant to charge the public with overutilizing benefits, reluctant to admit that the rationing of resources is entrenched public policy, but always quick to name the villain of the piece — the American physician, who is increasingly depicted as a thief in the night.

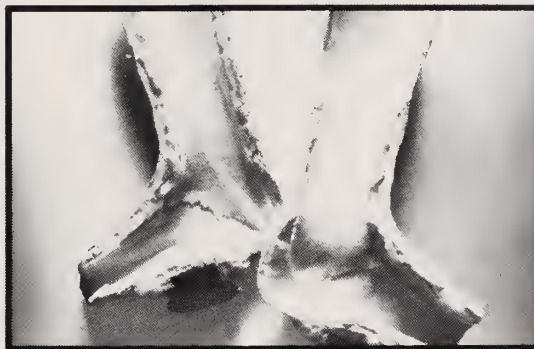
I began this month's column with a quotation from Hippocrates. In closing I would like to parody it as Hippocrates himself might have done had he practiced in the United States of the late 1980s:

"Wherever the art of medicine is held in contempt, there is also contempt for humanity."

Given time, all bureaucrats develop an abiding contempt for the people. Their contempt for doctors, those easy and safe whipping boys, is only camouflage for their hatred of the people (particularly sick people and people in pain) like the cortisone patient. I am afraid it is going to get much worse before it gets better. 

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*Carl A. Grote, Jr., M.D.
President, MASA*

Can Unions Save Medicine?

During this period of turmoil in dealing with third parties, I am reminded of a physician who has repeated this suggestion to me:

"What we really need to do is form a labor union."

At first glance this might seem to help solve some of our problems in dealing with those who seem to control our destiny at present. Other professional groups have unionized and, on the surface, might seem to have better control than we do.

This alternative has been addressed many times in the past, and on several occasions by the American Medical Association. At the annual meeting in Chicago in June 1987 this concept was the subject of Report BBB from the AMA Board of Trustees. After reading this report two or three times, I must admit I do not fully understand all of the legalities encompassed here. Nevertheless, I have used this report as source material for this column.

As it turns out, all professions do not have the right to organize under the National Labor Relations Act (NLRB). NLRB does give employees the right to organize and attempt to improve the terms and conditions of their employment. The purpose of such organization must be for collective bargaining.

Collective bargaining involves a good-faith attempt by any employer and labor organization to reach an agreement regarding wages, hours and working conditions. At first this may sound good. However, under

a sharper focus, one finds that physicians of the state do not qualify as employees, nor do they have a common employer to bargain with.

Most physicians would more likely qualify as independent contractors than employees. As an independent contractor you do not have the right to organize. There are certain groups of physicians working for hospitals, clinics and alternative delivery systems who do qualify as employees and have been able to organize under NLRB.

Certainly I would not attempt to advise anyone, in this short space, who can and cannot organize. I only wish to say that it is only under specific conditions and terms that a group of physicians is able to organize under prevailing law. Another problem: few of us realize that even if we organized as a labor union we would still be subject to the same anti-trust laws that encumber us as a medical association.

The report of the AMA Board of Trustees emphatically suggests that there are as many avenues for accomplishing some of our objectives as a medical society or association as there are through unionism.

The report lists five areas in which medical societies or associations can actively represent the economic interests of their members consistent with the anti-trust laws.

1. Advocacy of positions with the insurers and providers. That is, medical groups can advocate reim-

bursement should be made with specific entities or increased for specific procedures. The limitations are that a medical society must not threaten to engage in any type of boycott. Nor may it discuss specific fee levels.

2. Medical societies can establish a competitive enterprise. That is to say, medical societies or associations may form HMOs or IPAs. Under these entities they can engage in certain forms of bargaining activities.

3. Economic and entrepreneurial. That is to say a medical association may counsel its members on anything to do with economics or entrepreneurial activities. Societies can give their membership access to certain expertise in this respect.

4. Political and judicial action. Medical associations can seek to advance the interest of their members in legislatures and before regulatory bodies. They can also bring legal action against conduct that is adversarial.

5. They can lend assistance to employed physicians.

The conclusion of Report BBB is that as much can probably be accomplished as a medical association or society as through union organization.

No one is more concerned than your President and your Board of Censors over how to deal with the di-

lemmas facing us all each day. At present, we are exploring every possible avenue. We want to represent our membership and to do things that will be in your best interest. However, we do not want to strike out blindly. Therefore we are seeking the best legal help available before engaging in any activity with an unpredictable outcome.

The paramount concern I think we need to keep in mind in all of this is this: we want to remain as the patient's advocate. Certainly we are interested in the economic aspects of many of the rapidly changing events. Our personal welfare should not be our only concern. We want to preserve, above all, an environment where we can treat patients to the best of our ability and achieve the best results possible and not be forced to constantly look over our shoulders and concern ourselves with things that are not in the patient's best interest.

We did not become physicians to litigate, but to heal. I believe that we must all remind ourselves of that on a routine basis, no matter how infuriated we become with marketplace manipulations by those with economic power. □

Carl

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Custom Hip and Knee Prosthesis for Limb-Salvage Treatment of Primary Bone Tumors

Kenneth A. Jaffe, M.D.*
William K. Dunham, M.D.†

Abstract

This paper reviews the experience at the University of Alabama in treating 17 primary bone tumors involving the hip and knee region with limb-salvage surgery and reconstruction using a custom endoprosthesis. This procedure allows a complete removal of the tumor while preserving the extremity with a satisfactory cosmetic and functional result. There were 7 osteogenic sarcomas, 7 chondrosarcomas, 1 clear cell sarcoma, 1 malignant fibrocystic histiocytoma and 1 giant cell tumor. Followup averaged 27 months. The average age of the patients was 47 years (range 19-72). The functional results of 4 excellent, 6 good, 7 fair, and 0 poor were based upon the criteria of the Musculoskeletal Tumor Society for limb-salvage surgery. Most patients were able to ambulate without support or only with one cane. The major factor contributing to less good results was in the category of strength and stability. Overall, this is a very satisfactory method of treatment for primary bone tumors involving the hip and knee region.

In treating patients with either a soft tissue sarcoma or a primary bone tumor, the goal is to eliminate the primary tumor and to prevent local recurrence and distant metastasis. Recent advances in orthopaedic surgical techniques coupled with adjuvant chemotherapy and radiation therapy have contributed enormously to the ultimate survival and continued functional capacity in these patients.¹⁻³

Surgical resection has always had a major role in the treatment of these tumors.⁴ The traditional and classic approach had been ablative surgery.⁵ Initial attempts to locally resect the tumors were largely abandoned in the early 1900's because of the very high local recurrence rate. Therefore, amputation was adopted as the only procedure that offered a chance for local disease control.⁶ However, even radical operations have been plagued with a 10% to 25% local recurrence rate in some series.⁷ The reasons for this very high local failure are most likely related to microscopic extension of tumor beyond the excision field.

Does amputation give a better protection against distant tumor spread than locally radical removal of a malignant bone tumor? This question cannot yet be answered by yes or no. It is well known that circulatory tumor cells can be demonstrated, at least as long as the primary tumor has not been removed. It seems unlikely, then, that the type of surgery as such should have an influence on the metastasizing capacity of the tumor, provided that the tumor removal is complete. These arguments would speak in favor of conservative surgery, by which a useful limb function would be preserved.⁸

* Orthopaedic Resident, University of Alabama at Birmingham.

† Professor of Surgery, University of Alabama at Birmingham. Department of Surgery, Division of Orthopaedics/Orthopaedic Oncology University of Alabama at Birmingham. Reprint Requests: William K. Dunham, M.D., University of Alabama at Birmingham, 619 19th Street South, Birmingham, Alabama 35233.



39-year-old female — Clear Cell Sarcoma — proximal femur

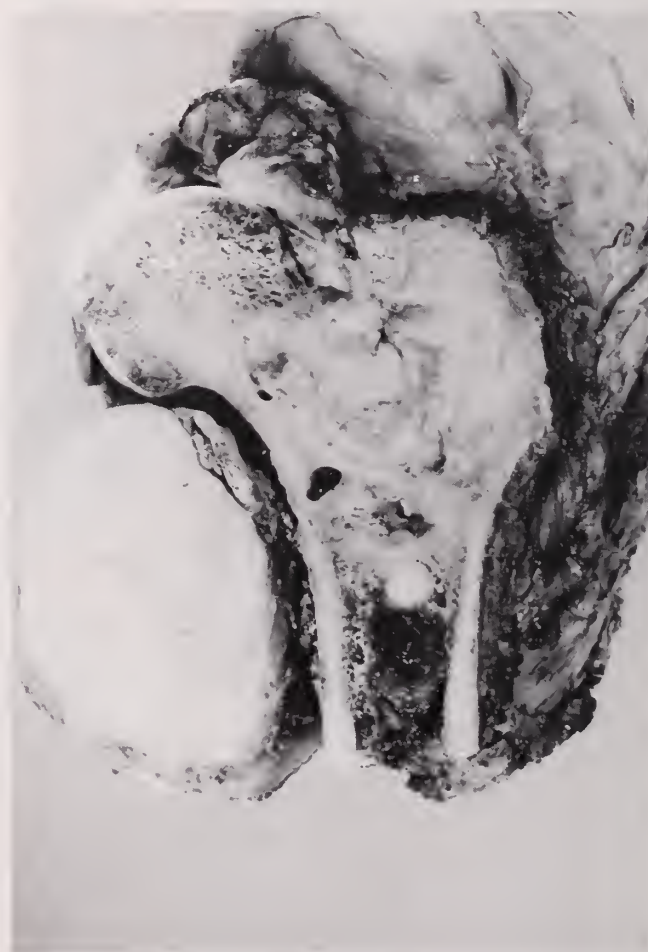
Limb sparing surgery is a procedure that removes a soft tissue or bone sarcoma while preserving the extremity with a satisfactory functional and cosmetic result.⁴ This is the preferred approach in the management of patients with high grade sarcomas when local disease can be completely resected.^{6, 8-10} Because of the risk of local recurrence, other therapeutic modalities may be used in conjunction with surgery such as radiation and chemotherapy. The rationale of preoperative treatment for high risk sarcomas is based upon the recognition that certain chemotherapeutic agents have significant antisarcoma activity¹¹ and further that they can enhance the effects of concomitant irradiation therapy.⁷ Theoretically, the sequential use of chemotherapy and irradiation therapy preoperatively can more effectively sterilize the periphery of the tumor bed than either alone, although this has not been proven in a controlled clinical trial.

There are situations when limb sparing surgery may not be indicated. These include the following: (1) Lesions of the extremities in which it is impossible to achieve adequate surgical margins and still achieve soft tissue closure and (2) Primary lesions that involve major vessels and nerves, either at the proximal extremity or in a site that will critically compromise function. Metastatic disease is not necessarily a contraindication for limb-sparing surgery.⁴

Children under the age of 10 years with osteosarcoma and who have anticipated growth remaining in the unaffected limb are generally considered for amputation or the Van Ness rotation plasty.¹¹ With limb-sparing surgery, they would have a limb length discrepancy inadequate for function when resection of the tumor includes the growth plates in the involved extremity.


Primary malignant bone tumors frequently occur in the hip, knee, and shoulder areas. Local radical surgery often involves the resection of part of a joint or the

entire joint. Depending on the extent of the tumor, particularly if it is extraosseously situated, a certain amount of the surrounding soft tissues may have to be included in the resected specimen. The functional aspects of such vast removal on limb preservation have to be calculated against the functional results after amputation.⁸ Reconstruction should provide limb function that is equal to or superior to the function of a prosthetic device.¹³ Following resection, there are several methods that have been described for reconstruction. These include arthrodesis with or without autologous bone transplants, allografts, custom made endoprosthesis, and prosthesis combined with allografts. This paper reviews the experience at the University of Alabama of reconstruction following limb-salvage procedures around the hip and knee region with custom made endoprosthetics. We believe that this is a suitable method in selected cases.



Resected specimen — 20 cm. proximal femoral section including soft tissue component.

continued on page 15



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COMPARATIVE PHARMACOLOGY OF THREE ANALGESICS

	CONSTIPATION	RESPIRATORY DEPRESSION	SEDATION	EMESIS	PHYSICAL DEPENDENCE
HYDROCODONE		X			X
CODEINE	X	X	X	X	X
OXYCODONE	XX	XX	XX	XX	XX

Blank space indicates that no such activity has been reported.

Table adapted from Facts and Comparisons (Nov.) 1984 and Catalano RB. The medical approach to management of pain caused by cancer. "Semin Oncol" 1975; 2; 379-92 and Reuler JB, et. al. The chronic pain syndrome: misconceptions and management. "Ann Intern Med" 1980; 93; 588-96.

- ◆ Vicodin offers: less nausea, less sedation, less constipation.

**...and longer lasting pain relief—
up to 6 hours.**

- ◆ Vicodin contains hydrocodone not codeine. In one study, 10 mg. of hydrocodone alone was shown to be as effective as 60 mg. of codeine.¹
- ◆ In a double-blind study, Vicodin (2 tablets), provided longer lasting pain relief than 60 mg. of codeine.²

Plus...

- ◆ Vicodin offers the convenience of CIII prescribing.
- ◆ Dosage flexibility—1 tablet every 6 hours or 2 tablets every 6 hours (up to 8 tablets in 24 hours).

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hydrocodone bitartrate 5 mg. (Warning: May be habit forming) with acetaminophen 500 mg.

The original hydrocodone analgesic.

Specify "Dispense as written" for the original hydrocodone analgesic.

INDICATIONS AND USAGE: For the relief of moderate to moderately severe pain.

CONTRAINDICATIONS: Hypersensitivity to acetaminophen or hydrocodone.

WARNINGS:

Drug Abuse and Dependence: VICODIN® is subject to the Federal Controlled Substances Act (Schedule III). Psychic dependence, physical dependence and tolerance may develop upon repeated administration of narcotics; therefore, VICODIN should be prescribed and administered with the same caution appropriate to the use of other oral-narcotic-containing medications.

Respiratory Depression: At high doses or in sensitive patients, hydrocodone may produce dose-related respiratory depression by acting directly on brain stem respiratory centers. Hydrocodone also affects centers that control respiratory rhythm, and may produce irregular and periodic breathing.

Head Injury and Increased Intracranial Pressure: The respiratory depressant effects of narcotics and their capacity to elevate cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury, other intracranial lesions or a preexisting increase in intracranial pressure. Furthermore, narcotics produce adverse reactions which may obscure the clinical course of patients with head injuries.

Acute Abdominal Conditions: The administration of narcotics may obscure the diagnosis or clinical course of patients with acute abdominal conditions.

PRECAUTIONS:

Special Risk Patients: VICODIN should be used with caution in elderly or debilitated patients and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, prostatic hypertrophy or urethral stricture.

Information For Patients: VICODIN, like all narcotics, may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery; patients should be cautioned accordingly.

Cough Reflex: Hydrocodone suppresses the cough reflex; caution should be exercised when VICODIN is used postoperatively and in patients with pulmonary disease.

Drug Interactions: The CNS-depressant effects of VICODIN may be additive with that of other CNS depressants. When combined therapy is contemplated, the dose of one or both agents should be reduced. The use of MAO inhibitors or tricyclic antidepressants with hydrocodone preparations may increase the effect of either the antidepressant or hydrocodone. The concurrent use of anticholinergics with hydrocodone may produce paralytic ileus.

Use in Pregnancy: Pregnancy Category C. Hydrocodone has been shown to be teratogenic in hamsters when given in doses 700 times the human dose. There are no adequate and well-controlled studies in pregnant women. VICODIN should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nonteratogenic Effects: Babies born to mothers who have been taking opioids regularly prior to delivery will be physically dependent. The intensity of the syndrome does not always correlate with the duration of maternal opioid use or dose.

Labor and Delivery: Administration of VICODIN to the mother shortly before delivery may result in some degree of respiratory depression in the newborn, especially if higher doses are used.

Nursing Mothers: It is not known whether this drug is excreted in human milk; therefore, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS:

Central Nervous System: Sedation, drowsiness, mental clouding, lethargy, impairment of mental and physical performance, anxiety, fear, dysphoria, dizziness, psychic dependence, mood changes.

Gastrointestinal System: Nausea and vomiting may occur; they are more frequent in ambulatory than in recumbent patients. Prolonged administration of VICODIN may produce constipation.

Genitourinary System: Ureteral spasm, spasm of vesical sphincters and urinary retention have been reported.

Respiratory Depression: (See WARNINGS.)

DOSAGE AND ADMINISTRATION: Dosage should be adjusted according to the severity of the pain and the response of the patient. However, tolerance to hydrocodone can develop with continued use, and the incidence of untoward effects is dose related.

The usual dose is one tablet every six hours as needed for pain. (If necessary, this dose may be repeated at four-hour intervals.) In cases of more severe pain, two tablets every six hours (up to eight tablets in 24 hours) may be required.

Revised, April 1982.

5685

1. Hopkinson JH III: *Curr Ther Res* 24: 503-516, 1978
2. Beaver, WT *Arch Intern Med*, 141:293-300, 1981.

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Methods and Materials:

Between October of 1980 and October of 1986, 17 patients with primary bone tumors of the hip and knee region have been treated at the University of Alabama without amputation using a custom endoprosthesis for reconstruction. There were 8 custom hip and 9 custom knee prostheses. Seven of these patients had osteogenic sarcoma, 7 chondrosarcoma, 1 clear cell sarcoma, 1 malignant fibrocystic histiocytoma and 1 giant cell tumor. The patients were staged according to Enneking as follows: 3 IB, 13 IIB, 0 III.¹⁴ A thorough pre-operative evaluation was performed prior to any surgery. This included biplane X-rays, computerized tomography of the lesion and the chest, and routine laboratory studies. Radionuclide scanning has become very helpful in staging and defining the tumor extent. Magnetic resonance imaging has only recently become available. Its value lies in evaluating the soft tissue mass and it may be very accurate in defining the extent of osseous involvement.^{15, 16} Biopsy of the lesion is essential to the diagnosis and staging. The fashion by which the biopsy is performed may adversely influence the chance of limb preservation.^{17, 18} An open biopsy was performed through an incision that could be easily excised during subsequent en bloc resections. Arteriography is less effective in defining the limits of the lesion but can more accurately assess the location and involvement of the major vessels by the tumor and a catheter is positioned in a major vessel perfusing the tumor to be used for the intra-arterial chemotherapy. The method used to treat 5 of these patients with high grade sarcomas was that described by Morton at UCLA.^{3, 6, 9} The patients received pre-operative intra-arterial Adriamycin (30mg/day \times 3½ days) and radiation therapy (1750 rads over 5 days).

Surgical removal of the tumor was then accomplished either by wide resection or marginal resection. We attempted to take a margin of normal tissue in all planes (wide resection). This was accomplished in 12 of the 17 cases. The other 5 cases had their tumor removed by a marginal resection. This means that at least one of the surgical margins was through reactive tissue or pseudocapsule at an edge of the tumor. The marginal excision was done when the proximity of the tumor to the vital vessels and nerves allowed no wide margin short of an amputation. After the margins of resection were planned, a custom prosthesis was fabricated using the limb scanogram calibrated for anticipated resection and length. The time for manufacture was 21 days and this interval was utilized for the administration of the chemotherapy and radiation therapy.



Area of resected tumor

Results

The followup of these 17 patients averaged 28 months (range 2-66). There were no local recurrences, 4 patients had metastasis and 3 died. Five patients received post-operative systemic chemotherapy and 3 patients received intra-arterial Adriamycin and local radiation because of a more malignant tumor than was assessed on biopsy specimen. One patient dislocated his hip in the perioperative period requiring closed reduction under general anesthesia. There was 1 hematoma and 2 infections requiring irrigation and debridement with no sequelae. The average length of resection for the proximal femur was 21 cm. and distal femur 20 cm. There were no complications related to prosthetic failure (ie. loosening or breakage). The functional results were based upon the criteria of the Musculoskeletal Tumor Society for evaluation following limb-salvage surgery.¹⁹ The primary factors considered are: (1) motion (2) pain (3) stability/deformity (4) strength (5) emotional acceptance/functional activities and (6) complications. Overall there were 4 excellent, 6 good, 7 fair, and no poor results.



Custom prosthesis in place

Discussion

The development of limb-sparing surgery using prosthetic devices has been in part a combination of the search of orthopaedists for improved methods of dealing with skeletal defects, deformed bony structures, and destroyed joints, and has borrowed heavily from all of the other disciplines within orthopaedics.^{13, 20} Recent advances with design and materials have made even large reconstructions a comparatively safe procedure. There are inherent problems with prosthetics. These include: (1) attachment of tendons to metal (2) ability to withstand wear and tear for decades and (3) loosening of the components.¹³

For limb-sparing surgery proper selection of patients and surgical planning is mandatory. The aim is eradication of the disease and the resection must be adequate according to the well established principles of oncologic surgery.²¹ The extent of resection can now be more meticulously and safely calculated with the aid of computerized tomography, scintigraphy, and magnetic resonance imaging. Relative contraindications for wide resection are involvement of major nerves and vessels. The resection of nerves frequently leads to an anesthetic foot. However, with proper care akin to diabetic foot counseling, patients can tolerate relative insensitivity without significant morbidity. The use of saphenous or prosthetic arterial grafts have been used in the face of vascular invasion.

In lesions involving the proximal femur the length resected depends on the extent of the osseous lesion. The surgical approach is posterior with the patient in the lateral position to give wide exposure. The excised muscle mass usually involves the iliopsoas, gluteus medius, gluteus minimus, and occasionally the gluteus maximus muscle. The femoral neurovascular struc-



Radiograph of bipolar custom total hip prosthesis



29 year-old female— high grade osteosarcoma of the distal femur

tures are isolated anteriorly and the sciatic nerve is isolated and protected posteriorly.²⁰ A proximal femur replacement prosthesis with a bipolar head is then inserted for reconstruction. Total hip arthroplasty is occasionally utilized. Patients have done extremely well in terms of ambulation, but due to the weakness of the abductors, a cane is often required for ambulation to prevent a significant gluteus lurch.

For lesions of the distal femur or proximal tibia, utilization of a custom made segmental prosthesis with total knee replacement provides an effective means of restoring skeletal continuity while maintaining the function of the knee joint. Surgery is carried out with the patient in the supine position. A medial approach is utilized which will easily allow the femoral and popliteal artery to be identified although other approaches are often dictated by the location of the biopsy incision or previous surgery. If the joint is free of tumor, part of the quadriceps mechanism and the patella can be retained and is necessary for a functioning knee joint. If the joint is potentially involved, or in extracompartmental lesions, an adequate resection usually requires removal of the distal femur or proximal tibia with its surrounding capsule, ligaments, and muscles. Because the resection necessitates sacrificing the knee ligament stabilizers, the resulting lack of stability requires a semi constrained total knee replacement such as the Noiles rotating hinge design. This prosthesis has an inherent rotation that helps dissipate the stresses that cause failure in the totally constrained hinge prosthesis. Skin and soft tissue coverage for the proximal tibial lesion is difficult at times and requires gastrocnemius muscle flaps and skin grafts.

An alternative to endoprosthetics for reconstruction following resection of the distal femur or proximal tibia is arthrodesis of the knee with an intra-medullary

rod and segmental bone grafting.^{22, 23} Although the inability to bend the knee is a functional handicap and an inconvenience to the patient, this procedure provides a stable, pain-free, weight bearing extremity.²⁴



AP radiograph of osteosarcoma — distal femur

Patient	Diagnosis	Site	Followup Mo.	Age	Sex	Stage
1. HG	CSA	R Prox Fem	4	72	M	IIB
2. SJ	Parosteal OSA	L Dist Fem	60	35	F	IB
3. DK	OSA	L Dist Fem	12	29	F	IIB
4. CC	Paraosteal OSA	L Dist Fem	29	53	M	IB
5. LB	OSA	L Prox Fem	66	65	F	IIB
6. HD	Chondrosarcoma	R Prox Fem	13	64	M	IIB
7. EP	Chondrosarcoma	R Prox Fem	15	71	M	IB
8. MP	Clear Cell Sar	L Prox Fem	2	39	F	IIB
9. HH	GCT	R Prox Fem	36	34	M	
10. TS	OSA	R Dist Fem	12	19	M	IIB
11. CT	Chondrosarcoma	R Prox Fem	43	58	M	IIB
12. DM	Parosteal OSA	L Dist Fem	48	32	F	IIB
13. EM	Chondrosarcoma	L Prox Fem	53	62	F	IIB
14. BE	OSA	R Dist Fem	5	59	F	IIB
15. CS	Chondrosarcoma	L Prox Tib	12	21	M	IIB
16. PS	Chondrosarcoma	R Dist Fem	25	35	F	IIB
17. JB	MFH	L Dist Fem	28	47	M	IIB

<i>Resection</i>	<i>Resected Length cm.</i>	<i>Functional Evaluation</i>	<i>Adjuvant Preop</i>	<i>Therapy Postop</i>	<i>Mets</i>	<i>Death</i>	<i>Complications</i>
Wide	18	Fair			—	—	
Wide	45	Excellent			—	—	
Wide	15	Good	IA Rad	Sys	—	—	
Wide	17	Excellent			—	—	
Wide	40	Fair	IA Rad	Sys	+	+	Infection
Wide	20	Good			—	—	
Wide	11	Good			—	—	
Marginal	20	Fair		IA Rad, Sys	—	—	Wound Hematoma
Marginal	11*	Good			—	—	
Marginal	20	Excellent	IA Rad	Sys	+	—	
Marginal	20	Fair			—	—	Dislocation
Marginal	15	Fair	IA Rad	IA Rad, Sys	—	—	
Wide	20	Fair			—	—	
Wide	20	Fair	IA Rad		+	+	Wound Infection
Wide	30	Excellent	IA Rad		—	—	
Wide	5	Good			—	—	
Wide	21	Good		Sys	+	+	

* Intraleisional

This is the recommended procedure in the young patient or in someone who might abuse the limb because of occupational requirements or body habitus. It has been shown that the large autografts for fusion will heal in the face of pre-operative and post-operative Adriamycin chemotherapy.²³

Allograft replacement is another reasonable alternative for reconstruction. There is a high incidence of infection, fracture and osteonecrosis, but if these complications can be avoided, the results have been good.²⁴

Conclusion

In final summary, the overall results of limb-salvage surgery using an endoprosthesis for reconstruction is very satisfactory. A good or satisfactory weight bearing capacity is generally achieved, and most patients are able to walk on flat ground with one stick or even without support. Improvements with the technique are being developed. These include: (1) better materials to withstand wear (2) improved fixation methods such as porous ingrowth and (3) modular component design to possibly construct the appropriate device in the operating room from stocked components and having the users ability to change component dimensions should the extent of the tumor vary from pre-operative evaluation. The problems of tumor recurrence or metastasis should be evaluated independently from the functional results. Improvements in pre-operative and post-operative chemotherapy have contributed significantly to survival but controlled prospective studies are needed. Another area of improvement is the recognition of the disease sufficiently early to avoid distant metastasis and enable more patients to benefit from en bloc resection. □



Lateral view of custom knee prosthesis



Custom total knee prosthesis in place

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BRIEF SUMMARY

CONTRAINDICATIONS

There are no known contraindications to the use of sucralfate.

PRECAUTIONS

Duodenal ulcer is a chronic, recurrent disease. While short-term treatment with sucralfate can result in complete healing of the ulcer, a successful course of treatment with sucralfate should not be expected to alter the post-healing frequency or severity of duodenal ulceration.

Drug Interactions: Animal studies have shown that the simultaneous administration of CARAFATE with tetracycline, phenytoin, or cimetidine will result in a statistically significant reduction in the bioavailability of these agents. This interaction appears to be nonsystemic in origin, presumably resulting from these agents being bound by CARAFATE in the gastrointestinal tract. The bioavailability of these agents may be restored simply by separating the administration of these agents from that of CARAFATE by two hours. The clinical significance of these animal studies is yet to be defined.

Carcinogenesis, Mutagenesis, Impairment of Fertility: No evidence of drug-related tumorigenicity was found in chronic oral toxicity studies of 24 months' duration conducted in mice and rats at doses up to 1 gm/kg (12 times the human dose). A reproduction study in rats at doses up to 38 times the human dose did not reveal any indication of fertility impairment. Mutagenicity studies have not been conducted.

Pregnancy: Pregnancy Category B. Teratogenicity studies have been performed in mice, rats, and rabbits at doses up to 50 times the human dose and have revealed no evidence of harm to the fetus due to sucralfate. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when sucralfate is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Adverse reactions to sucralfate in clinical trials were minor and only rarely led to discontinuation of the drug. In studies involving over 2,500 patients, adverse effects were reported in 121 (4.7%). Constipation was the most frequent complaint (2.2%). Other adverse effects, reported in no more than one of every 350 patients, were diarrhea, nausea, gastric discomfort, indigestion, dry mouth, rash, pruritus, back pain, dizziness, sleepiness, and vertigo.

DOSAGE AND ADMINISTRATION

The recommended adult oral dosage for duodenal ulcer is 1 gm four times a day on an empty stomach.

Antacids may be prescribed as needed for relief of pain but should not be taken within one-half hour before or after sucralfate.

While healing with sucralfate may occur during the first week or two, treatment should be continued for 4 to 8 weeks unless healing has been demonstrated by x-ray or endoscopic examination.

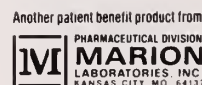
HOW SUPPLIED

CARAFATE (sucralfate) 1-gm pink tablets are supplied in bottles of 100 and in Unit Dose Identification Paks of 100. The tablets are embossed with MARION/1712.

Issued 3/84

References:

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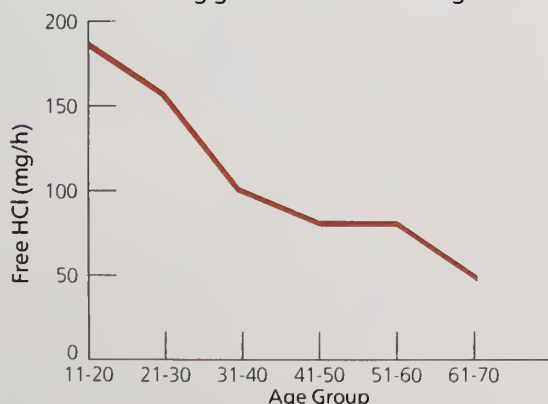
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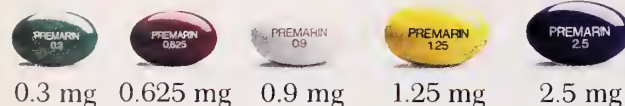
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BRIEF SUMMARY (FOR FULL PRESCRIBING INFORMATION AND PATIENT INFORMATION SEE PACKAGE CIRCULARS)

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PREMARIN[®] Brand of conjugated estrogens Vaginal Cream, in a nonliquefying base

1 ESTROGENS HAVE BEEN REPORTED TO INCREASE THE RISK OF ENDOMETRIAL CARCINOMA

Three independent, case-controlled studies have reported an increased risk of endometrial cancer in postmenopausal women exposed to exogenous estrogens for more than one year. This risk was independent of the other known risk factors for endometrial cancer. These studies are further supported by the finding that incidence rates of endometrial cancer have increased sharply since 1969 in eight different areas of the United States with population-based cancer reporting systems, an increase which may be related to the rapidly expanding use of estrogens during the last decade. The three case-controlled studies reported that the risk of endometrial cancer in estrogen users was about 4.5 to 13.9 times greater than in nonusers. The risk appears to depend on both duration of treatment and on estrogen dose. In view of these findings, when estrogens are used for the treatment of menopausal symptoms, the lowest dose that will control symptoms should be utilized and medication should be discontinued as soon as possible. When prolonged treatment is medically indicated, the patient should be reassessed on at least a semi-annual basis to determine the need for continued therapy. Although the evidence must be considered preliminary, one study suggests that cyclic administration of low doses of estrogen may carry less risk than continuous administration, if therefore appears prudent to utilize such a regimen. Close clinical surveillance of all women taking estrogens is important. In all cases of undiagnosed persistent or recurring abnormal vaginal bleeding, adequate diagnostic measures should be undertaken to rule out malignancy. There is no evidence at present that "natural" estrogens are more or less hazardous than "synthetic" estrogens at equi-estrogenic doses.

2 ESTROGENS SHOULD NOT BE USED DURING PREGNANCY

The use of female sex hormones, both estrogens and progestogens, during early pregnancy may seriously damage the offspring. It has been shown that females exposed in utero to diethylstilbestrol, a nonsteroidal estrogen, have an increased risk of developing, in later life, a form of vaginal or cervical cancer that is ordinarily extremely rare. This risk has been estimated as not greater than 4 per 1,000 exposures. Furthermore, a high percentage of such exposed women (from 30% to 90%) have been found to have vaginal adenosis, epithelial changes of the vagina and cervix. Although these changes are histologically benign, it is not known whether they are precursors of malignancy. Although similar data are not available with the use of other estrogens, it cannot be presumed they would not induce similar changes. Several reports suggest an association between intrauterine exposure to female sex hormones and congenital anomalies, including congenital heart defects and limb-reduction defects. One case-controlled study estimated a 4-7 fold increased risk of limb-reduction defects in infants exposed in utero to sex hormones (oral contraceptives, hormone withdrawal tests for pregnancy, or attempted treatment for threatened abortion). Some of these exposures were very short and involved only a few days of treatment. The data suggest that the risk of limb-reduction defects in exposed fetuses is somewhat less than 1 per 1,000. In the past, female sex hormones have been used during pregnancy in an attempt to treat threatened or habitual abortion. There is considerable evidence that estrogens are ineffective for these indications, and there is no evidence from well-controlled studies that progestogens are effective for these uses. If PREMARIN is used during pregnancy, or if the patient becomes pregnant while taking this drug, she should be apprised of the potential risks to the fetus, and the advisability of pregnancy continuation.

DESCRIPTION: PREMARIN (conjugated estrogens, USP) contains a mixture of estrogens, obtained exclusively from natural sources, blended to represent the average composition of material derived from pregnant mares' urine. It contains estrone, equin, and 17 α -dihydroequilin, together with smaller amounts of 17 α -estradiol, equilenin, and 17 α -dihydroequilin as salts of their sulfate esters. Tablets are available in 0.3 mg, 0.625 mg, 0.9 mg, 1.25 mg, and 2.5 mg strengths of conjugated estrogens. Cream is available as 0.625 mg conjugated estrogens per gram.

INDICATIONS AND USAGE: PREMARIN (conjugated estrogens tablets, USP). Moderate-to-severe vasomotor symptoms associated with the menopause (There is no evidence that estrogens are effective for nervous symptoms or depression without associated vasomotor symptoms and they should not be used to treat such conditions.) Osteoporosis (abnormally low bone mass). Atrophic vaginitis. Kraurosis vulvae. Female castration. PREMARIN (conjugated estrogens) Vaginal Cream is indicated in the treatment of atrophic vaginitis and kraurosis vulvae.

PREMARIN HAS NOT BEEN SHOWN TO BE EFFECTIVE FOR ANY PURPOSE DURING PREGNANCY AND ITS USE MAY CAUSE SEVERE HARM TO THE FETUS (SEE BOXED WARNING).

Concomitant Progestin Use: The lowest effective dose appropriate for the specific indication should be utilized. Studies of the addition of a progestin for 7 or more days of a cycle of estrogen administration have reported a lowered incidence of endometrial hyperplasia. Morphological and biochemical studies of the endometrium suggest that 10 to 13 days of progestin are needed to provide maximal maturation of the endometrium and to eliminate any hyperplastic changes. Whether this will provide protection from endometrial carcinoma has not been clearly established. There are possible additional risks which may be associated with the inclusion of progestin in estrogen replacement regimens (See PRECAUTIONS). The choice of progestin and dosage may be important; product labeling should be reviewed to minimize possible adverse effects.

CONTRAINDICATIONS: Estrogens should not be used in women (or men) with any of the following conditions: 1. Known or suspected cancer of the breast except in appropriately selected patients being treated for metastatic disease. 2. Known or suspected estrogen-dependent neoplasia. 3. Known or suspected pregnancy (See Boxed Warning). 4. Undiagnosed abnormal genital bleeding. 5. Active thrombophlebitis or thromboembolic disorders. 6. A past history of thrombophlebitis, thrombosis, or thromboembolic disorders associated with previous estrogen use (except when used in treatment of breast or prostatic malignancy).

WARNINGS: Estrogens have been reported to increase the risk of endometrial carcinoma (see Boxed Warning). However, a recent large, case-controlled study indicated no increase in risk of breast cancer in postmenopausal women. A recent study has reported a 2- to 3-fold increase in the risk of surgically confirmed gallbladder disease in women receiving postmenopausal estrogens.

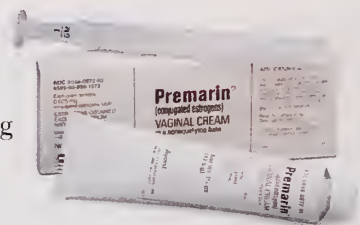
Adverse effects of oral contraceptives may be expected at the larger doses of estrogen used to treat prostatic or breast cancer or postpartum breast engorgement, it has been shown that there is an increased risk of thrombosis in men receiving estrogens for prostatic cancer and women for postpartum breast engorgement. Users of oral contraceptives have an increased risk of diseases, such as thrombophlebitis, pulmonary embolism, stroke, and myocardial infarction. Cases of retinal thrombosis, mesenteric thrombosis, and optic neuritis have been reported in oral contraceptive users. An increased risk of postsurgery thromboembolic complications has also been reported in users of oral contraceptives. If feasible, estrogen should be discontinued at least 4 weeks before surgery of the type associated with an increased risk of thromboembolism, or during periods of prolonged immobilization. Estrogens should not be used in persons with active thrombophlebitis, thromboembolic disorders, or in persons with a history of such disorders in association with estrogen use. They should be used with caution in patients with cerebral vascular or coronary artery disease. Large doses (5 mg conjugated estrogens per day), comparable to those used to treat cancer of the prostate and breast, have been shown to increase the risk of nonfatal myocardial infarction, pulmonary embolism, and thrombophlebitis. When doses of this size are used, any of the thromboembolic and thrombotic adverse effects should be considered a clear risk.

For atrophic vaginitis

PREMARIN[®] (conjugated estrogens)

Vaginal Cream

0.625 mg/g



Benign hepatic adenomas should be considered in estrogen users having abdominal pain and tenderness, abdominal mass, or hypovolemic shock. Hepatocellular carcinoma has been reported in women taking estrogen-containing oral contraceptives. Increased blood pressure may occur with use of estrogens in the menopause and blood pressure should be monitored with estrogen use. A worsening of glucose tolerance has been observed in patients on estrogen-containing oral contraceptives. For this reason, diabetic patients should be carefully observed. Estrogens may lead to severe hypercalcemia in patients with breast cancer and bone metastases.

PRECAUTIONS: Physical examination and a complete medical and family history should be taken prior to the initiation of any estrogen therapy with special reference to blood pressure, breasts, abdomen, and pelvic organs, and should include a Papanicolaou smear. As a general rule, estrogen should not be prescribed for longer than one year without another physical examination being performed. Conditions influenced by fluid retention, such as asthma, epilepsy, migraine, and cardiac or renal dysfunction, require careful observation. Certain patients may develop manifestations of excessive estrogenic stimulation, such as abnormal or excessive uterine bleeding, mastodynia, etc. Prolonged administration of unopposed estrogen therapy has been reported to increase the risk of endometrial hyperplasia in some patients. Oral contraceptives appear to be associated with an increased incidence of mental depression. Patients with a history of depression should be carefully observed. Pre-existing uterine leiomyomata may increase in size during estrogen use. The pathologist should be advised of estrogen therapy when relevant specimens are submitted. If jaundice develops in any patient receiving estrogen, the medication should be discontinued while the cause is investigated. Estrogens should be used with care in patients with impaired liver function, renal insufficiency, metabolic bone diseases associated with hypercalcemia, or in young patients in whom bone growth is not yet complete. If concomitant progestin therapy is used, potential risks may include adverse effects on carbohydrate and lipid metabolism.

The following changes may be expected with larger doses of estrogen:

- a. Increased subfibrinolytic fibrin retention
- b. Increased prothrombin and factors VII, VIII, IX, and X, decreased antithrombin 3, increased norepinephrine-induced platelet aggregability
- c. Increased thyroid binding globulin (TBG) leading to increased circulating total thyroid hormone, as measured by PBI, T₄ by column, or T₄ by radioimmunoassay. Free T₃ resin uptake is decreased, reflecting the elevated TBG. Free T₄ concentration is unaltered.
- d. Impaired glucose tolerance
- e. Decreased pregnandiol excretion
- f. Reduced response to methylglucoside test
- g. Reduced serum folate concentration
- h. Increased serum triglyceride and phospholipid concentration

As a general principle, the administration of any drug to nursing mothers should be done only when clearly necessary since many drugs are excreted in human milk.

Long-term, continuous administration of natural and synthetic estrogens in certain animal species increases the frequency of carcinomas of the breast, cervix, vagina, and liver. However, in a recent, large case-controlled study of postmenopausal women there was no increase in risk of breast cancer with use of conjugated estrogens.

ADVERSE REACTIONS: The following have been reported with estrogenic therapy including oral contraceptives: breakthrough bleeding, spotting, change in menstrual flow, dysmenorrhea, premenstrual-like syndrome, amenorrhea during and after treatment, increase in size of uterine fibromyoma, vaginal candidiasis, change in cervical erosion and in degree of cervical secretion, cystitis-like syndrome, tenderness, enlargement, secretion (of breasts), nausea, vomiting, abdominal cramps, bloating, cholestatic jaundice, chloasma or melasma which may persist when drug is discontinued, erythema multiforme, erythema nodosum, hemorrhagic eruption, loss of scalp hair, hirsutism, sleepiness of corneal curvature, intolerance to contact lenses, headache, migraine, dizziness, mental depression, chorea, increase or decrease in weight, reduced carbohydrate tolerance, aggravation of porphyria, edema, changes in libido.

ACUTE OVERDOSAGE: May cause nausea, and withdrawal bleeding may occur in females.

DOSAGE AND ADMINISTRATION:

PREMARIN[®] Brand of conjugated estrogens tablets, USP

1. Given cyclically for short-term use only. For treatment of moderate-to-severe vasomotor symptoms, atrophic vaginitis, or kraurosis vulvae associated with the menopause (0.3 mg to 1.25 mg or more daily). The lowest dose that will control symptoms should be chosen and medication should be discontinued as promptly as possible. Administration should be cyclic (eg, three weeks on and one week off). Attempts to discontinue or taper medication should be made at three- to six-month intervals.

2. Given cyclically. Osteoporosis. Female castration. Osteoporosis — 0.625 mg daily. Administration should be cyclic (eg, three weeks on and one week off). Female castration — 1.25 mg daily, cyclically. Adjust upward or downward according to response of the patient. For maintenance, adjust dosage to lowest level that will provide effective control.

Patients with an intact uterus should be monitored for signs of endometrial cancer and appropriate measures taken to rule out malignancy in the event of persistent or recurring abnormal vaginal bleeding.

PREMARIN[®] Brand of conjugated estrogens Vaginal Cream

Given cyclically for short-term use only. For treatment of atrophic vaginitis or kraurosis vulvae.

The lowest dose that will control symptoms should be chosen and medication should be discontinued as promptly as possible.

Administration should be cyclic (eg, three weeks on and one week off).

Attempts to discontinue or taper medication should be made at three- to six-month intervals.

Usual dosage range: 2 g to 4 g daily, intravaginally, depending on the severity of the condition.

Treated patients with an intact uterus should be monitored closely for signs of endometrial cancer and appropriate diagnostic measures should be taken to rule out malignancy in the event of persistent or recurring abnormal vaginal bleeding.

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Brunneroma

A Case Report

T. Nagendran, M.D.*
Franklin Imm, M.D.† and
Karyn L. Butler‡

Benign duodenal tumors are rare representing only 0.008% of surgical and autopsy specimens.¹ This rarity is attributed to the relative less time of contact with carcinogens as opposed to colon and stomach where the incidence of cancer is high.²

Some of the benign tumors arising from duodenum are: leiomyoma, lipoma, carcinoid, and ectopic pancreatic tissue and Brunneromas. Among these Brunneromas or Brunner's gland, adenoma represents 10.6%.¹ Brunner's glands are peculiar to small intestine. They were first described by Brunner in 1688³ and are located, for the most part, in the first portion of the duodenum.⁴ Brunner's glands extend into submucosa and empty into crypts of Leiberkuhn. The normal physiologic function of these glands is not known. Grossman⁵ suggests that alkaline secretion of Brunner's glands protects the duodenal mucosa from the acid chyme and indeed hyperplasia may result from increased stimulation by acid.

Brunneromas are rare and described first by Salvioli in 1872.³ Since that time, there have been less than 100 reported cases in English literature. They are mostly

found in the duodenal bulb and are usually 1-2 cm in diameter, and range from a few millimeters to 8 cm.

The etiology of these tumors is not known. They are considered to be hamartomas with a predominance of Brunner's gland elements. Goldman⁶ showed that in most cases there is an admixture of both acinar and ductular elements which would be unusual for either hyperplasia or neoplasia. They are not considered to be pre-malignant. Only one case of cancer in Brunneroma has been reported in the literature.⁷

The clinical presentation is nonspecific and includes: a) vague abdominal pain or discomfort; b) vomiting in cases of duodenal obstruction; c) upper GI bleeding, like in our case (this is usually associated with erosion or ulceration; and d) extra-hepatic biliary obstruction.⁸ DeCastella⁹ reported 52% of patients with upper abdominal discomfort, 43% with bleeding, and 24% with melena needing blood transfusion. Radiologically, these tumors cannot be differentiated from other benign tumors of the duodenum. Usually there is a sessile and/or polypoid smooth walled filling defect in the duodenal bulb.⁴

Treatment is local excision when they are symptomatic. Gastroduodenoscopy will decide open vs endoscopic removal of these tumors. In our case, absence of pedicle forced us to remove the lesion via celiotomy.

* Chief of staff, VAMC, Montgomery.

† Assist. Chief, Laboratory Service, Tuskegee VAMC.

‡ 4th-year Medical Student, Morehouse School of Medicine, Atlanta, GA.



Figure 1. GI showing duodenal polyp.

Endoscopic removal can be done a) if the lesion is small; b) if they are pediculated; and c) if ampulla of Vater can be identified easily.¹⁰

Case History

This 65-year-old, Caucasian, male veteran was admitted to the Medical Service of Tuskegee VAMC in October 1985 with massive upper GI bleeding. A gastroduodenoscopy was done on admission but, due to a large amount of blood, the visibility was poor. The patient was treated with nasogastric suction, intravenous fluids, blood transfusions, and H₂ blockers. He stopped bleeding. Before discharge, an upper gastrointestinal series was done and revealed a 2 cm smooth filling defect in the duodenal bulb. (Fig. 1) A repeat endoscopy was done but the Brunneroma was not seen.

The patient was discharged on antacids. He was readmitted in March 1986 with upper gastro-intestinal bleeding. After initial resuscitation, an endoscopy confirmed the polypoid lesion in the duodenum with no evidence of active bleeding. A pedicle could not be readily seen; so, the lesion was not removed through the scope. At celiotomy, the lesion was found to be a sessile polypoid lesion. (Fig. 2) □

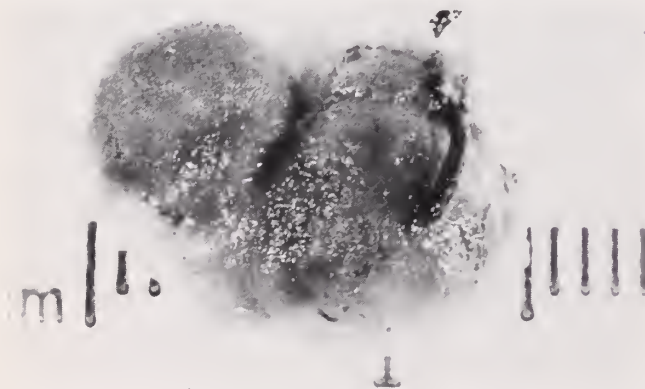
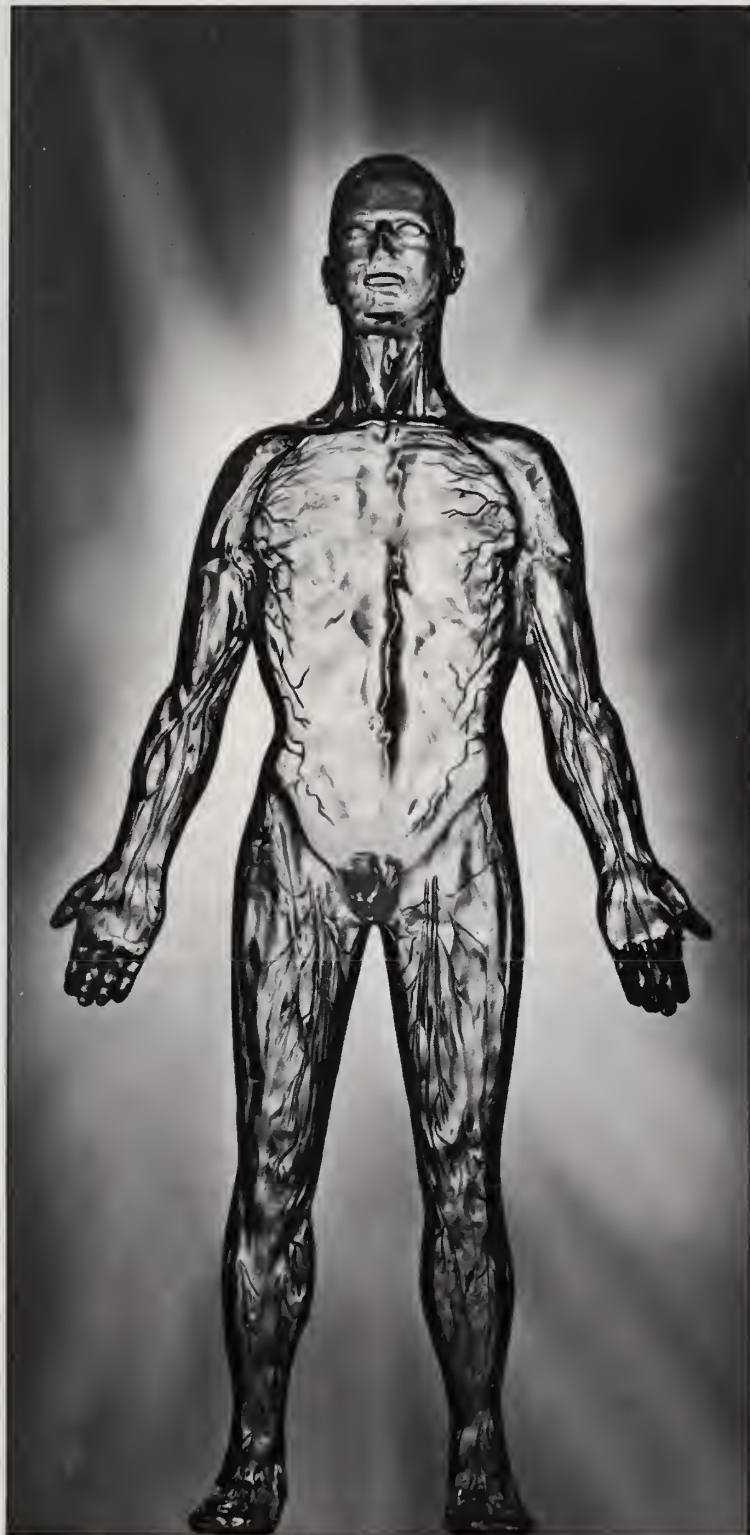


Figure 2. Duodenal polyp.

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Pediatrics (and Medicine) Then and Now

C. Kermit Pitt, M.D., F.A.A.P.*

Editor, Alabama Medicine:

C. Kermit Pitt, M.D., has been a clinical faculty member here at the School of Primary Medical Care for the past 10 years. From time to time during that period he has shared with students and residents his observations and experiences about the changes in medicine in the Tennessee Valley which have occurred over the past 40 years. Our students, residents and faculty have benefited tremendously from his recollections, reflections and evaluations, and his predictions for the future.

It was my feeling that the physicians of Alabama and elsewhere would also enjoy and benefit from his extraordinary fund of knowledge. At my request, Dr. Pitt agreed to write this informative and delightful article. It strikes me that these two words also describe Dr. Pitt — informative and delightful.

* Clinical Professor of Pediatrics, School of Primary Medical Care, The University of Alabama in Huntsville.

John R. Montgomery, M.D., Professor and Chief of Pediatric Programs, School of Primary Care, The University of Alabama in Huntsville.

Environmental Statistics

The population of Decatur, Alabama in 1940 was 17,000 and that of Huntsville 17,000. Decatur General Hospital was an institution of fifty beds. There was no clinical laboratory and no X-ray department. Laboratory and X-ray work was done by a nurse or the physician himself. The only X-ray machine was a small portable one. A newborn nursery with running water was years in the future.

Physicians in Morgan County numbered 26 (more than 100 today) and in Madison County 29 (now about 300). All members of the medical profession in Morgan except two were general practitioners. The two specialists did eye, ear, nose and throat, were largely self-taught but performed creditably. North Alabama's only American Board certified specialist was an internist in Florence.

Entering medical school fifty-two years ago (1935), I began work in Decatur in the autumn of 1940 and became the first Board certified physician in Morgan County.

Lest anything in this paper be misinterpreted, I wish to emphasize that my respect for our family and general practitioners has always been nothing but great and I

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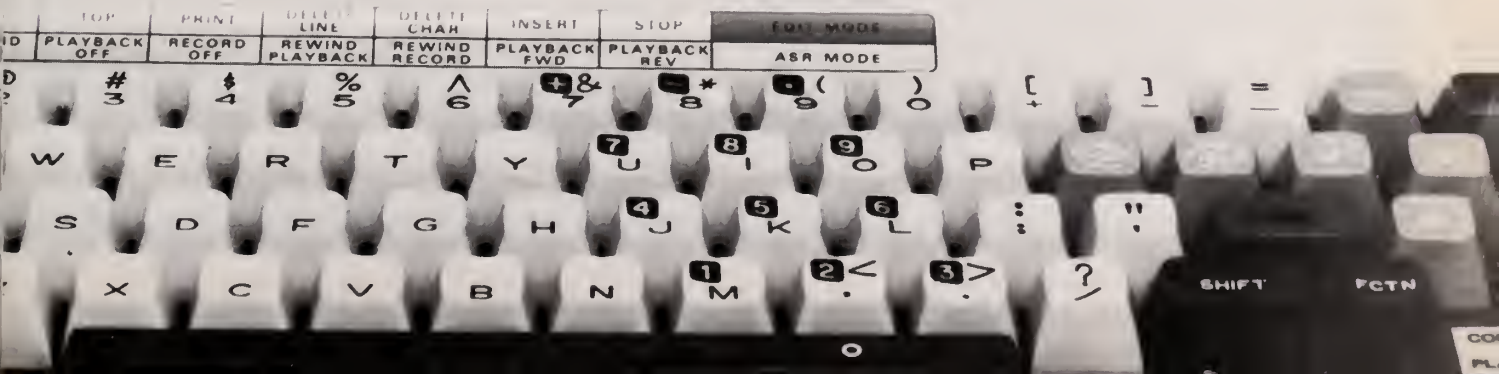
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have more than once remarked to pediatric colleagues that if we are not diligent they will do better child care than we.

A few national statistics may be of interest. The American Academy of Pediatrics was formed in 1930 with 1000 physicians limiting practice to the specialty. The American Board was organized in 1933 and in the following twenty years 5,360 physicians were certified. At the present time the number exceeds 36,000. A 1948 national survey indicated less than 5,000 pediatricians in the United States. Half of these were members of the Academy and seventy-five percent were in cities of greater than 50,000 population. Fifty percent had less than one year of formal pediatric training. Twelve percent of all child health care was provided by pediatricians. Seventy-five percent was by general practitioners whose average formal pediatric training was less than one month.

Physicians in North Alabama in the decades of 1930 and 1940 were office based but still made many home visits. It was not unusual for the busy doctor to make ten to twenty such calls in one day. Deliveries were almost all in the home and usually without anaesthesia, or with, at most, a few breaths of chloroform. Annual evaluation of health status, growth and development was practically unknown. Office and house calls were almost entirely for treatment of disease.

Practice expense was minimal and income taxes insignificant. Accounts were often paid on annual basis and many people resented reception of statements by mail ("duns").

The average pediatrician's fee for an office visit was two to three dollars as compared with twenty-five or more today. A well known and revered physician, near retirement, once told me that his gross income the first year was less than twenty dollars. He also said that he had never mailed a statement for services.

Medical liability suits were rare and judgements in favor of plaintiffs even more so. This is in contrast to conditions which exist today. In fact, during the first 100 years of this nation less than thirty medical malpractice cases were recorded in the appeals courts. Cost of liability insurance was insignificant. Today one in every five physicians has a pending or actual suit against him or her and more than 75,000 such litigations occur annually. A few years ago a medical liability award of more than a million dollars had never been made by a jury. Last year more than 250 such awards were granted. In our state a single award was in excess of twenty million. Fortunately, the judge made a reduction. Nationally, the average award is now almost one million. Some of our nation's 400 billion health care bill may be attributed to excessive and redundant di-

agnostic and treatment procedures made necessary by the need to practice defensive medicine. Premiums are astounding. Florida and New York's Long Island obstetricians now pay above 100,000 dollars and their neurosurgeons more than 150,000 annually. Next year Alabama obstetricians, those still in practice, and neurosurgeons expect to pay 60,000 dollars or more. Premiums for pediatricians, though considerably less than those, are significant in their influence upon the perceived necessity to practice defensive medicine and, thereby, increase cost of care.

The 1940 national mortality rate for infants was 49 per 1000 live births (61 in Alabama). The rate for 1986 was 10.4 (Alabama 13.4). Maternal rates for those years were 40 per 10,000 live births and less than one. Overall, life expectancy has increased by more than six years since 1940 (about 30 years in the last century) and today the average female infant may expect to live until 78-80 years of age and the male to 71-2.

Drugs and Immunizing Agents

The 1935 arsenal of drugs included and was largely limited to quinine, crude digitalis, morphine, a few arsenicals, one insulin, calomel. Prior to that time no patient enjoyed aid from sulfa drugs, penicillins, streptomycins, cephalosporins, aminoglycosides, steroids, bronchodilators, beta-blockers and agonists, antithyroid drugs, oncology medicines, anti-depressants and the hosts of other present day therapeutics.

The first sulfa drug, sulfanilamide, became available the year I entered medical school, 1935. A crude injectable form of penicillin came in 1943 and streptomycin in 1946. Prior to the availability of these and subsequent, not mislabeled, miracle drugs numerous infections were invariably fatal. Among them were tuberculous meningitis, miliary tuberculosis, bacterial endocarditis.

Immunizing agents were new, few and under used. Smallpox and typhoid vaccines were best known but diphtheria, tetanus and pertussis in early use. Few people expected the near availability of measles, mumps or poliomyelitis vaccines. Hepatitis and influenza vaccines were decades away.

Diagnostic facilities were sparse and relatively underdeveloped. Some X-ray and cardiographic machines were in use but, surely, few had dreamed of Cat-scanners, ultrasound or magnetic resonance imaging.

Surgery

Fifty years ago surgery was a respected specialty about to explode into incredible expansion. Chest surgery was in its infancy and no appreciable amount of cardiovascular work in progress. In 1938 Robert Gross, pediatric surgeon at Children's Hospital, Boston, did the first patent ductus correction and a few years later Dr. Blalock at Hopkins performed the first successful

Tetralogy of Fallot operation and soon this procedure and its modifications by Willis Potts, Chicago Children's Hospital pediatric surgeon, became useful worldwide. Quickly, scores of cardiac procedures to mend congenital and acquired defects were developed resulting in innumerable lives saved for useful and happy existence.

In North Alabama pyloric stenosis went largely unrecognized and rarely, if ever, corrected. In fact, during the first fifteen years of my practice the surgery for this condition in Decatur was done by me. The number averaged about two annually. My experience had been acquired from serving as intern assistant to pioneer pediatric surgeons George Packard of Denver and Warner Duckett of Dallas. Seeing these helpless, and apparently hopeless, infants transformed into vigorous, healthy and normal babies was gratifying indeed. When trained surgeons arrived on the scene in our area I gladly relinquished responsibility for such activity. Things have never been quite the same.

The remarkable development of surgery in all its fields has been attended and made possible by parallel sophisticated anaesthesiology. From open drip ether and chloroform to the methods and agents of today was indeed a pilgrimage of progress.

Infant Feeding

Half-century ago there were no prepared infant foods. Available formulae included evaporated milk, lactic acid milk, buttermilk and, rarely, goat's milk. Of course, there were breasts in those days but as suppliers of nutrition for babies they were less popular than today. Large quantities of formula, frequently as much as two quarts daily, were fed until eighteen months of age and iron deficiency anemia commonly required treatment. Many presented with hemoglobin levels of five and six grams and transfusions of blood were often given. With the advent of prepared foods the pendulum swung in the other direction so that most pediatricians and other feeders of infants were prone to start solid foods at extremely early ages. Now, as we all know, the pendulum is in the backswing and there is the tendency to delay solid food until five or six months or later. My conviction holds that babies are more happy and, perhaps, more healthy when some solids, selected with discretion, are introduced in early months of life. Aware that such practice entails the possibility of developing certain allergic conditions, I suggest judgement and moderation at both ends of the extreme.

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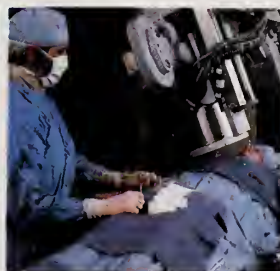
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Obviously, the most important recent improvement in infant nutrition is the emphasis, once again, on the importance of breast feeding. Of the mothers with whom I worked in recent years, ninety percent or more attempted, usually successfully, to breast feed. This is in comparison with fifteen or twenty percent some years ago. A few of my readers may remember a statement made in a meeting years ago by Dr. Dawson, admired pediatrician of Montgomery, Alabama, that if mothers would consider their breasts a means of infant feeding rather than as pieces of amusement, their babies would be better nourished.

Diseases

Prior to World War II, as many as one million children each year suffered measles, one quarter of a million had pertussis and an equal number diphtheria. More than twenty thousand developed paralytic poliomyelitis. Pulmonary and central nervous system complications of whooping cough were frequent and approximately one of each four babies under six months of age died. Hospitals serving an appreciable number of children were always alert for the appearance of the critically ill, strangling diphtheria patient and the death rate was very high. Most people were in great terror of poliomyelitis. Today, a few hundred cases of pertussis are news-worthy and diphtheria and poliomyelitis are almost non-existent. Let none doubt that the use of immunizing agents is responsible for this happy circumstance.

Through the 1930-40 decade typhoid fever was prevalent and attended by high mortality and morbidity. There was no effective antibiotic. It was a dreadful, month long disease attended by high fever, much debilitation and many complications. The *Decatur Daily* for July 23-28, 1934 reported a recent county epidemic of twelve cases with three deaths.

As a pediatric resident in Denver in 1940, I was impressed by the importance of rheumatic fever and rheumatic heart disease. At that time the leading cause of death in the Children's Hospital was rheumatic heart disease and, although I have seen less than six cases of Sydenham's chorea in forty-six years of practice, I experienced some twenty in one year in Denver. Also, during the first fifteen years of practice I treated forty-five patients with acute rheumatic fever, but have not seen a single case in the last thirty years. Although many factors influence the occurrence of this disease and voices are being heard that suggest otherwise, it is my opinion that the treatment of streptococcal infections with promptness has been the major factor in the decline of this tremendous problem of yesteryear.

Interesting, and somewhat alarming, are reports within the last three years of rather marked increase in emerging cases of acute rheumatic fever. Forty new cases from the Children's Hospital, Columbus, Ohio, seventeen from the Children's Hospital, Pittsburgh and ninety-nine from the state of Utah have been reported. Other clusters have occurred in Dallas, Denver and Akron.

Incidentally, for reasons not understood, Colorado has been an area particularly conducive to rheumatic fever. During World War II there were fifty thousand cases of this disease in service men. Of these twenty-five percent occurred in that state.

The national mortality rate for tuberculosis in 1900 was 200 per 100,000 population and essentially 100 percent of people above the age of fifteen years were skin test positive. By the end of the next decade the disease was still a national problem and one of the leading causes of death in the country. As late as 1940 it was the leading cause between ages fifteen and twenty-four years. There were no effective drugs and many people were treated in hospitals and out-patient clinics with the only means available, namely, nutrition, rest and artificial pneumothorax. Since then the need for the seven or eight Alabama tuberculosis sanatoria has become non-existent and those few patients who are still unfortunate enough to develop the malady are effectively treated at home or in general hospitals and usually quickly returned to activity.

Between 1948 and 1950 intradermal tuberculin tests on 780 children under nineteen years of age were done in my office. Of these, six and one-half percent were positive. At about the same time Welch and Berry in Birmingham, Alabama did similar tests on 924 white children and 1200 blacks. Eight percent of the white and nineteen percent of the black children were positive. Skin tests are still done on a 1-2 year schedule, but positives are uncommon in our area.

In 1940, large syphilis public health clinics were held in Decatur. Patients were given very disagreeable injections twice weekly for eighteen months with some hope of recovery. Of course, today a few injections of penicillin for a brief period of time is quite adequate.

Scurvy and ricketts were still common. In our area the former was more frequent. My files contain a list of seventeen patients seen between 1949 and 1956. Some were dramatic. One was referred from a crippled children's outpatient clinic with the tentative diagnosis of paralytic poliomyelitis. It was gratifying to see him completely recover after a few doses of vitamin C.

Except for pinworms, intestinal parasites were much more common in North Alabama than today. Hookworm in my time was not much of a problem, but ascariasis was prevalent and I encountered it several times annually for a number of years. One youngster was reported to have vomited and passed by rectum a

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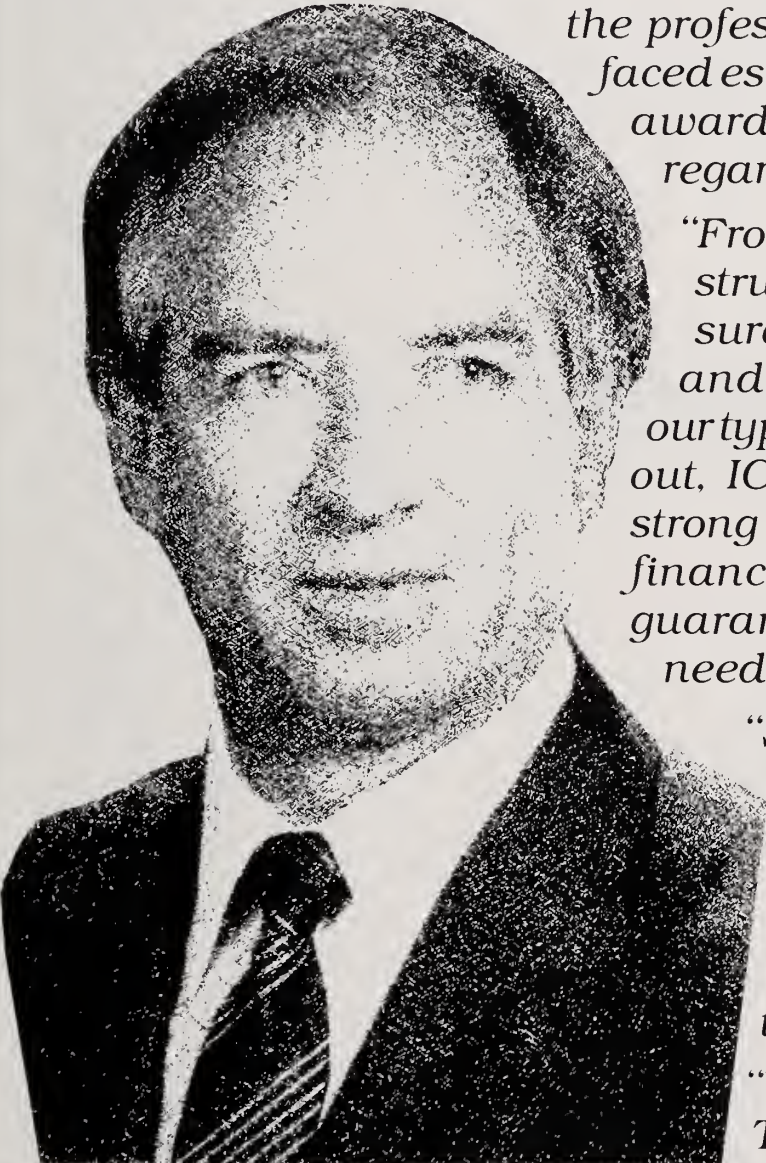
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total of over 300 of these long worms. She presented with intestinal obstruction, developed measles and promptly expired.

Few physicians who graduated from medical school in the last quarter of a century have experienced pellagra which was prevalent some years before. Well remembered are two patients who came to me many years ago. Under three years of age, these little sisters had classic findings of diarrhea and dermatitis, without dementia, and rapidly responded to nicotinamide. Some twenty years later the mother of these children called in great anxiety to report that one of them has recently delivered a baby and was having mental problems. Advised to consult her obstetrician, she happily reported a few days later her daughter's improvement which she, at least, attributed to the vitamin.

Again, almost none but older physicians remembers acrodynia. It was never frequent in this country, not not rare (nine cases in my practice), but was a never to be forgotten entity once encountered. The most irritable, restless, photophobic, often erythemic and hypotonic infants in my memory were victims of this condition. Several years ago the etiology was elucidated by Fanconi, Warkany and Hubbard and proven to be mercury sensitivity, usually by way of mercury ointments or calomel from teething powders. As late as 1952, prior to removal of calomel from teething powders, acrodynia accounted for 3.6 percent of all admissions to a children's hospital in England. The May, 1987 issue of *Pediatrics* reports a case of acrodynia due to exposure to mercury from broken fluorescent light bulbs.

Other examples of change in epidemiology and treatment of disease include pneumonia, for which there were no specific drugs prior to 1935. Mortality figures were in the range of 100 for each 100,000 people. By 1940, the use of sulfanilamide drugs had reduced these figures by at least fifty percent and after 1943, penicillin had made more dramatic reduction. Since etiologic diagnosis of pneumonia in early times was not so exact as now figures are less significant, but estimates of mortality from pneumococcal pneumonia in infants and small children in 1930 ranged from twenty to fifty percent as compared with less than one percent at the present time. Mycoplasma pneumonia was an unknown entity and viral rarely recognized. Hemophilus and staphylococcal pneumonia were devastating problems.

In my concern for the economics involved in health care I sometimes console myself by comparing the treatment of pneumonia sixty years ago and today. My relatively young grandmother's terminal illness was pneumonia. Her home, where she was treated, was

about ten miles from the small town where her physician lived. Traveling to see her daily for seven days, he managed her problem to the best of his ability without, of course, benefit of any specific antibiotic and on the ninth day she died. Her total bill must have been in the range of fifty to seventy-five dollars. This monetary cost to my grandfather represented about two months of his income. The family was prematurely and permanently deprived of wife and mother. Today the patient with the same illness would probably present at the office where history and physical examination, blood count, X-rays, blood culture and urinalysis would be done. Perhaps an injection and a prescription for oral medication would be given and the patient allowed to go home. She might well expect to be fever free in 48 hours, rapidly ambulatory and back in the office one week later for repeat examination and X-rays indicating complete recovery. The cost to her family might be in the range of two hundred dollars and represent the income from two or three days work. Most importantly, she was restored to health.

In pre-antibiotic days tuberculous meningitis was universally fatal and the pneumococcal type almost so. Hemophilus meningitis was fatal in almost all patients under two years of age, where eighty percent of cases occur. Meningococcal meningitis patients recovered occasionally. In 1943, Silverthorne reviewed 1100 cases of meningitis from the Hospital For Sick Children, Toronto, which had occurred between 1919 and 1941. All tuberculous ones died. Of 134 streptococcal ones only two recovered and of seventy hemophilus ones, with no chemotherapy, one lived. With serum and chemotherapy, 22 of 83 hemophilus patients survived.

At the present time pneumococcal meningitis in infancy still carries mortality of five to twenty percent. Hemophilus ranks next with mortality of approximately eight to fifteen percent, while less than five percent of uncomplicated meningococcal patients die.

To my knowledge, the first patient to survive tuberculous meningitis in Alabama was treated by me in the basement of the old Decatur General Hospital and reported in the *Journal of The Medical Association of Alabama* in May, 1950. In the same journal, in 1952, we reported the world literature's fifteenth case of galactosemia.

In Alabama in 1940 the leading cause of death in children between one and five years of age was diarrhea. At that time the only treatment of merit was fluid and sulfa drugs. Work of such people as Gambel and Darrow in the decade surrounding this date provided remarkable fluid and electrolyte help to those responsible for managing diarrhea and other diseases. The availability of antibiotics subsequently made the problem of infections of many kinds much less awesome.

continued on page 44

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NEW Keflet Tablets are available as:



Keflet is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillin-sensitive patients.

Brief Summary. Consult the package literature for prescribing information. Indications and Usage: Keflet[®] Tablets (cephalexin, Dista) are indicated for the treatment of the following infections when caused by susceptible strains of the designated microorganisms:

Respiratory tract infections caused by *Streptococcus pneumoniae* and group A β -hemolytic streptococci (Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. Keflet is generally effective in the eradication of streptococci from the nasopharynx; however, substantial data establishing the efficacy of Keflet in the subsequent prevention of rheumatic fever are not available at present.)

Otitis media due to *S. pneumoniae*, *Haemophilus influenzae*, staphylococci, streptococci, and *Neisseria catarrhalis*

Skin and skin structure infections caused by staphylococci and/or streptococci

Bone infections caused by staphylococci and/or *Proteus mirabilis*
Genitourinary tract infections, including acute prostatitis, caused by *Escherichia coli*, *P. mirabilis*, and *Klebsiella* sp.

Note: Culture and susceptibility tests should be initiated prior to and during therapy. Renal function studies should be performed when indicated.

Contraindication: Keflet is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

Warnings: BEFORE CEPHALEXIN THERAPY IS INSTITUTED, CAREFUL INQUIRY SHOULD BE MADE CONCERNING PREVIOUS HYPERSENSITIVITY REACTIONS TO CEPHALOSPORINS AND PENICILLIN. CEPHALOSPORIN C DERIVATIVES SHOULD BE GIVEN CAUTIOUSLY TO PENICILLIN-SENSITIVE PATIENTS.

SERIOUS ACUTE HYPERSENSITIVITY REACTIONS MAY REQUIRE EPINEPHRINE AND OTHER EMERGENCY MEASURES.

There is some clinical and laboratory evidence of partial cross-allergenicity of the penicillins and the cephalosporins. Patients have been reported to have had severe reactions (including anaphylaxis) to both drugs.

Any patient who has demonstrated some form of allergy, particularly to drugs, should receive antibiotics cautiously. No exception should be made with regard to Keflet.

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics (including macrolides, semisynthetic penicillins, and cephalosporins); therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with the use of antibiotics. Such colitis may range in severity from mild to life-threatening.

Treatment with broad-spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis.

Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone. In moderate to severe cases, management should include sigmoidoscopy, appropriate bacteriologic studies, and fluid, electrolyte, and protein supplementation. When the colitis does not improve after the drug has been discontinued, or when it is severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile*. Other causes of colitis should be ruled out.

Usage in Pregnancy: Safety of this product for use during pregnancy has not been established.

Precautions: *General:*—Patients should be followed carefully so that any side effects or unusual manifestations of drug idiosyncrasy may be detected. If an allergic reaction to Keflet occurs, the drug should be discontinued and the patient treated with the usual agents (eg, epinephrine or other pressor amines, antihistamines, or corticosteroids).

Prolonged use of Keflet may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics. In hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug.

Keflet should be administered with caution in the presence of markedly impaired renal function. Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended.

Indicated surgical procedures should be performed in conjunction with antibiotic therapy.

As a result of administration of Keflet, a false-positive reaction for glucose in the urine may occur. This has been observed with Benedict's and Fehling's solutions and also with Clinifast[®] tablets but not with Tes-Tape[®] (Glucose Enzymatic Test Strip, USP, Lilly).

Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Usage in Pregnancy—Pregnancy Category B—The daily oral administration of cephalexin to rats in doses of 250 or 500 mg/kg prior to and during pregnancy, or to rats and mice during the period of organogenesis only, had no adverse effect on fertility, fetal viability, fetal weight, or litter size. Note that the safety of cephalexin during pregnancy in humans has not been established.

Cephalexin showed no enhanced toxicity in weaning and newborn rats as compared with adult animals. Nevertheless, because the studies in humans cannot rule out the possibility of harm, Keflet should be used during pregnancy only if clearly needed.

Nursing Mothers:—The excretion of cephalexin in the milk increased up to 4 hours after a 500-mg dose, the drug reached a maximum level of 4 μ g/mL, then decreased gradually, and had disappeared 8 hours after administration. Caution should be exercised when Keflet is administered to a nursing woman.

Adverse Reactions: Gastrointestinal:—Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely. The most frequent side effect has been diarrhea. It was very rarely severe enough to warrant cessation of therapy. Dyspepsia and abdominal pain have also occurred. As with some penicillins and some other cephalosporins, transient hepatitis and cholestatic jaundice have been reported rarely.

Hypersensitivity:—Allergic reactions in the form of rash, urticaria, angioedema, and, rarely, erythema multiforme, Stevens-Johnson Syndrome, or toxic epidermal necrolysis have been observed. These reactions usually subsided upon discontinuation of the drug. Anaphylaxis has also been reported.

Other reactions have included genital and anal pruritus, genital moniliasis, vaginitis and vaginal discharge, dizziness, fatigue, and headache. Reversible interstitial nephritis has been reported rarely. Eosinophilia, neutropenia, thrombocytopenia, and slight elevations in SGOT and SGPT have been reported.


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"Living in the city
is lonely enough...
with herpes it's like
solitary confinement."

ZOVIRAX[®] (acyclovir) CAPSULES

**Prevent genital herpes
recurrences
month after month with
daily therapy.**

(In controlled studies, recurrences were totally prevented for 4 to 6 months in up to 75% of patients.)

*Please see last page of this advertisement for
brief summary of prescribing information.*

ZOVIRAX[®] (acyclovir) CAPSULES

**Help free your
patients from
recurrences.**

Daily therapy

Coping with genital herpes is rarely easy. For some, the worst part is the pain and discomfort of frequent attacks — month after month, year after year. For others, the emotional burden presents a more difficult problem, leading to social isolation, anxiety, and diminished self-esteem.

Prevent or reduce recurrences

Although your patients have to live with herpes, they shouldn't have to suffer. Daily therapy with ZOVIRAX CAPSULES can help free them from the cycle of recurrent genital herpes. For many, one capsule three times a day can suppress recurrences completely while on therapy.

Generally well tolerated

Daily therapy with ZOVIRAX CAPSULES is generally well tolerated. The most frequent adverse reactions reported during clinical trials were headache, diarrhea, nausea/vomiting, vertigo, and arthralgia.

The physical and emotional difficulties posed by genital herpes are unique for each patient. The frequency and severity of recurrent episodes, as well as the emotional impact of the disease, should be considered when selecting daily therapy with ZOVIRAX CAPSULES.

*Please see brief summary of
prescribing information on next page.*



Prevent recurrences month after month*

ZOVIRAX®

(acyclovir) CAPSULES

Brief Summary

INDICATIONS AND USAGE: Zovirax Capsules are indicated for the treatment of initial episodes and the management of recurrent episodes of genital herpes in certain patients.

The severity of disease is variable depending upon the immune status of the patient, the frequency and duration of episodes, and the degree of cutaneous or systemic involvement. These factors should determine patient management, which may include symptomatic support and counseling only, or the institution of specific therapy. The physical, emotional and psycho-social difficulties posed by herpes infections as well as the degree of debilitation, particularly in immunocompromised patients, are unique for each patient, and the physician should determine therapeutic alternatives based on his or her understanding of the individual patient's needs. Thus Zovirax Capsules are not appropriate in treating all genital herpes infections. The following guidelines may be useful in weighing the benefit/risk considerations in specific disease categories:

First Episodes (primary and nonprimary infections — commonly known as initial genital herpes):

Double-blind, placebo-controlled studies have demonstrated that orally administered Zovirax significantly reduced the duration of acute infection (detection of virus in lesions by tissue culture) and lesion healing. The duration of pain and new lesion formation was decreased in some patient groups. The promptness of initiation of therapy and/or the patient's prior exposure to Herpes simplex virus may influence the degree of benefit from therapy. Patients with mild disease may derive less benefit than those with more severe episodes. In patients with extremely severe episodes, in which prostration, central nervous system involvement, urinary retention or inability to take oral medication require hospitalization and more aggressive management, therapy may be best initiated with intravenous Zovirax.

Recurrent Episodes:

Double-blind, placebo-controlled studies in patients with frequent recurrences (6 or more episodes per year) have shown that Zovirax Capsules given for 4 to 6 months prevented or reduced the frequency and/or severity of recurrences in greater than 95% of patients. Clinical recurrences were prevented in 40 to 75% of patients. Some patients experienced increased severity of the first episode following cessation of therapy; the severity of subsequent episodes and the effect on the natural history of the disease are still under study.

The safety and efficacy of orally administered acyclovir in the suppression of frequent episodes of genital herpes have been established only for up to 6 months. Chronic suppressive therapy is most appropriate when, in the judgement of the physician, the benefits of such a regimen outweigh known or potential adverse effects. In general, Zovirax Capsules should not be used for the suppression of recurrent disease in mildly affected patients. Unanswered questions concerning the human relevance of *in vitro* mutagenicity studies and reproductive toxicity studies in animals given very high doses of acyclovir for short periods (see Carcinogenesis, Mutagenesis, Impairment of Fertility) should be borne in mind when designing long-term management for individual patients. Discussion of these issues with patients will provide them the opportunity to weigh the potential for toxicity against the severity of their disease. Thus, this regimen should be considered only for appropriate patients and only for six months until the results of ongoing studies allow a more precise evaluation of the benefit/risk assessment of prolonged therapy.

Limited studies have shown that there are certain patients for whom intermittent short-term treatment of recurrent episodes is effective. This approach may be more appropriate than a suppressive regimen in patients with infrequent recurrences.

Immunocompromised patients with recurrent herpes infections can be treated with either intermittent or chronic suppressive therapy. Clinically significant resistance, although rare, is more likely to be seen with prolonged or repeated therapy in severely immunocompromised patients with active lesions.

CONTRAINDICATIONS: Zovirax Capsules are contraindicated for patients who develop hypersensitivity or intolerance to the components of the formulation.

WARNINGS: Zovirax Capsules are intended for oral ingestion only.

PRECAUTIONS: General: Zovirax has caused decreased spermatogenesis at high doses in some animals and mutagenesis in some acute studies at high concentrations of drug (see PRECAUTIONS — Carcinogenesis, Mutagenesis, Impairment of Fertility). The recommended dosage and length of treatment should not be exceeded (see DOSAGE AND ADMINISTRATION).

Exposure of Herpes simplex isolates to acyclovir *in vitro* can lead to the emergence of less sensitive viruses. The possibility of the appearance of less sensitive viruses in man must be borne in mind when treating patients. The relationship between the *in vitro* sensitivity of Herpes simplex virus to acyclovir and clinical response to therapy has yet to be established.

Because of the possibility that less sensitive virus may be selected in patients who are receiving acyclovir, all patients should be advised to take particular care to avoid potential transmission of virus if active lesions are present while they are on therapy. In severely immunocompromised patients, the physician should be aware that prolonged or repeated courses of acyclovir may result in selection of resistant viruses which may not fully respond to continued acyclovir therapy.

Drug Interactions: Co-administration of probenecid with intravenous acyclovir has been shown to increase the mean half-life and the area under the concentration-time curve. Urinary excretion and renal clearance were correspondingly reduced.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Acyclovir was tested in lifetime bioassays in rats and mice at single daily doses of 50, 150 and 450 mg/kg given by gavage. There was no statistically significant difference in the incidence of tumors between treated and control animals, nor did acyclovir shorten the latency of tumors. In 2 *in vitro* cell transformation assays, used to provide preliminary assessment of potential oncogenicity in advance of these more definitive life-time bioassays in rodents, conflicting results were obtained. Acyclovir was positive at the highest dose used in one system and the resulting morphologically transformed cells formed tumors when inoculated into immunosuppressed, syngeneic, weanling mice. Acyclovir was negative in another transformation system considered less sensitive.

In acute studies, there was an increase, not statistically significant, in the incidence of chromosomal damage at maximum tolerated parenteral doses of 100 mg/kg acyclovir in rats but not Chinese hamsters; higher doses of 500 and 1000 mg/kg were clastogenic in Chinese hamsters. In addition, no activity was found after 5 days dosing in a dominant lethal study in mice. In 6 of 11 microbial and mammalian cell assays, no evidence of mutagenicity was observed. At 3 loci in a Chinese hamster ovary cell line, the results were inconclusive. In 2 mammalian cell assays (human lymphocytes and L5178Y mouse lymphoma cells *in vitro*), positive responses for mutagenicity and chromosomal damage occurred, but only at concentrations at least 400 times the acyclovir plasma levels achieved in man.

Acyclovir has not been shown to impair fertility or reproduction in mice (450 mg/kg/day, p.o.) or in rats (25 mg/kg/day, s.c.). At 50 mg/kg/day s.c. in the rat, there was a statistically significant increase in post-implantation loss, but no concomitant decrease in litter size. In female rabbits treated subcutaneously with acyclovir subsequent to mating, there was a statistically significant decrease in implantation efficiency but no concomitant decrease in litter size at a dose of 50 mg/kg/day. No effect upon implantation efficiency was observed when the same dose was administered intravenously. In a rat peri- and postnatal study at 50 mg/kg/day s.c., there was a statistically significant decrease in the group mean numbers of corpora lutea, total implantation sites and live fetuses in the F₁ generation. Although not statistically significant, there was also a dose related decrease in group mean numbers of live fetuses and implantation sites at 12.5 mg/kg/day and 25 mg/kg/day, s.c. The intravenous administration of 100 mg/kg/day, a dose known to cause obstructive nephropathy in rabbits, caused a significant increase in fetal resorptions and a corresponding decrease in litter size. However, at a

maximum tolerated intravenous dose of 50 mg/kg/day in rabbits, there were no drug-related reproductive effects.

Intraperitoneal doses of 320 or 80 mg/kg/day acyclovir given to rats for 1 and 6 months, respectively, caused testicular atrophy. Testicular atrophy was persistent through the 4-week postdose recovery phase after 320 mg/kg/day; some evidence of recovery of sperm production was evident 30 days post-dose. Intravenous doses of 100 and 200 mg/kg/day acyclovir given to dogs for 31 days caused aspermatogenesis. Testicles were normal in dogs given 50 mg/kg/day, i.v. for one month.

Pregnancy: Teratogenic Effects: Pregnancy Category C. Acyclovir was not teratogenic in the mouse (450 mg/kg/day, p.o.), rat (50 mg/kg/day, s.c.) or rabbit (50 mg/kg/day, s.c. and i.v.). There are no adequate and well-controlled studies in pregnant women. Acyclovir should not be used during pregnancy unless the potential benefit justifies the potential risk to the fetus. Although acyclovir was not teratogenic in animal studies, the drug's potential for causing chromosome breaks at high concentration should be taken into consideration in making this determination.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Zovirax is administered to a nursing woman. In nursing mothers, consideration should be given to not using acyclovir treatment or discontinuing breastfeeding.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS — Short-Term Administration: The most frequent adverse reactions reported during clinical trials were nausea and/or vomiting in 8 of 298 patient treatments (2.7%) and headache in 2 of 298 (0.6%). Less frequent adverse reactions, each of which occurred in 1 of 298 patient treatments (0.3%), included diarrhea, dizziness, anorexia, fatigue, edema, skin rash, leg pain, inguinal adenopathy, medication taste and sore throat.

Long-Term Administration: The most frequent adverse reactions reported in studies of daily therapy for 3 to 6 months were headache in 33 of 251 patients (13.1%), diarrhea in 22 of 251 (8.8%), nausea and/or vomiting in 20 of 251 (8.0%), vertigo in 9 of 251 (3.6%), and arthralgia in 9 of 251 (3.6%). Less frequent adverse reactions, each of which occurred in less than 3% of the 251 patients (see number of patients in parentheses), included skin rash (7), insomnia (4), fatigue (7), fever (4), palpitations (1), sore throat (2), superficial thrombophlebitis (1), muscle cramps (2), pars planitis (1), menstrual abnormality (4), acne (3), lymphadenopathy (2), irritability (1), accelerated hair loss (1), and depression (1).

DOSAGE AND ADMINISTRATION: Treatment of initial genital herpes: One 200 mg capsule every 4 hours, while awake, for a total of 5 capsules daily for 10 days (total 50 capsules).

Chronic suppressive therapy for recurrent disease: One 200 mg capsule 3 times daily for up to 6 months. Some patients may require more drug, up to one 200 mg capsule 5 times daily for up to 6 months.

Intermittent Therapy: One 200 mg capsule every 4 hours, while awake, for a total of 5 capsules daily for 5 days (total 25 capsules). Therapy should be initiated at the earliest sign or symptom (prodrome) of recurrence.

Patients With Acute or Chronic Renal Impairment: One 200 mg capsule every 12 hours is recommended for patients with creatinine clearance ≤ 10 ml/min/1.73 m².

HOW SUPPLIED: Zovirax Capsules (blue, opaque) containing 200 mg acyclovir and printed with "Wellcome ZOVIRAX 200" - Bottles of 100 (NDC-0081-0991-55) and unit dose pack of 100 (NDC-0081-0991-56).

Store at 15°-30°C (59°-86°F) and protect from light.

*In controlled studies, recurrences were totally prevented for 4 to 6 months in up to 75% of patients.

Burroughs Wellcome Co., Research Triangle Park, North Carolina 27709



The Tennessee Valley and in many other areas of the country malaria was one of the leading causes of morbidity and mortality. By 1940, TVA mosquito control had largely eliminated this menace from which so many had suffered, but people, both lay and professional, were so conscious of it that they were prone to consider any febrile illness as probable malaria until proven otherwise. Apparently, they had become accustomed to having febrile illness treated as malaria and if recovery was not satisfactory, other possible causes considered. Management of this disease was then little different from that of much more early times when Hippocrates gave a clear description of it and said that it could not be distinguished from other febrile illness until Cinchona, a specific treatment, was discovered. This drug was introduced in Europe in 1640 and quinine isolated from it in 1820.

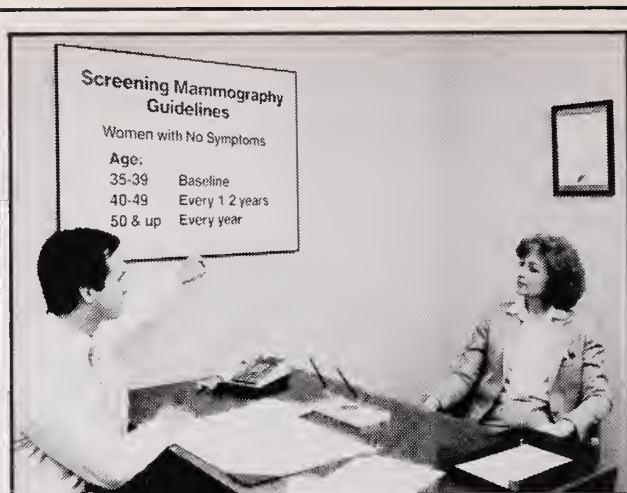
Although I have encountered no case of malaria for many years, the Alabama department of health, 1957, reported studies of 682 blood smears in a single year. Few were positive at that time, but in a peek year, 1929, over 10,000 cases of the disease were reported with 430 deaths in Alabama. An excerpt from the *Decatur Daily* dated October 1-6, 1934 gives some interesting insights into the importance attached to the problem in the minds of local citizens. "For some years we held malaria almost entirely in check in this section, thanks to the antimalaria campaigns put on in this area and assisted by state funds and public subscriptions. Then the depression, and then the deluge of mosquitoes. . . .

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"Then, brother and sister, there'll be shoutin' in the Valley."

In conclusion, the last fifty years have been attended by more progress in health care than that of all previously recorded history. Of course, advances in many fields have been comparable. For instance, a few of us have witnessed transportation evolve from the ox cart to the moon rocket.

It does seem fair to observe that my generation has enjoyed the education, stimulation and the innumerable rewards of living in the "Golden Age" of medicine and it is tempting to predict and lament the probability that a period so glorious may come not again, but universal infinity, the mind of man and Divine inspiration make that prediction less than certain. □



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continued on page 48

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continued from page 47

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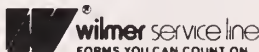
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Foods that may help reduce the risk of gastrointestinal and respiratory tract cancer are cabbage, broccoli, brussels sprouts, kohlrabi, cauliflower.

Fruits, vegetables and whole-grain cereals such as oatmeal, bran and wheat may help lower the risk of colorectal cancer.

Foods high in fats, salt- or nitrite-cured foods such as ham, and fish and types of sausages smoked by traditional methods should be eaten in moderation.

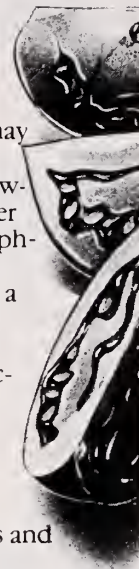
Be moderate in consumption of alcohol also.

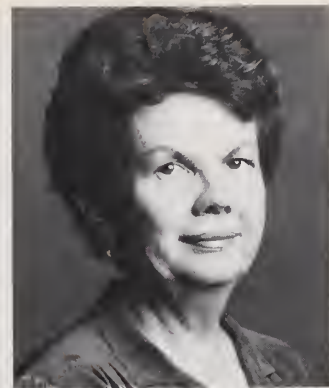
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AIDS and Its Victims

As public and professional awareness of AIDS expands, so, too, does concern and confusion. These conditions, unfortunately, exist among both the public and physicians.

Of particular concern is how AIDS affects the public in general and also the danger of AIDS in innocent children and heterosexuals. A recent survey in Alabama showed a high percentage of people knew that AIDS was transmitted through sex and IV drug use but many also thought that drinking after someone with AIDS, handling money and breathing the same air with an AIDS victim was dangerous.

The wearing of gloves, as well as other protective clothing is seen outside hospitals today. Dentists, morticians, law enforcement officers and even boxing referees are urged to protect themselves from contact from possible AIDS virus.

AIDS is the first sexually transmitted disease of pandemic proportions. Unlike syphilis, it has no cure and is fatal. Two of every three new AIDS cases still involve homosexuals, but the killer is rapidly closing in on drug users and on heterosexuals, who by 1991 will account for 1 in 11 new cases.

Robert Gallo of the National Cancer Institute in Bethesda, Maryland and one of the pioneers in AIDS research, describes what he believes is one of the ways the AIDS virus might work: "Like Greeks hidden inside the Trojan horse, the AIDS virus enters the body concealed inside a helper T cell from an infected host. Almost always it arrives as a passenger in blood or semen. It kills the one lymphocyte most critical to the immune response: the helper T cell."

One big question is at what risk are heterosexuals? Bisexual males pose one of the biggest threats to the heterosexual community. Bisexual husbands lead a double life. Ultimately they will infect their wives. Health professionals are worried that the absence of "group ties" among bisexuals such as homosexuals have and their real fear of losing their wives and children make them the hardest to reach of the AIDS-carrying groups.

The average age of AIDS victims is 28. They cannot afford the necessary care. Twenty-five percent have no insurance. Our youth have not prepared for catastrophic illness. The young face the same sudden familiarity with death from AIDS as do soldiers during war.

In recent months both Ann Landers and Abigail Van Buren have been educating readers on AIDS in response to letters seeking advice. Some of their advice has been: People with AIDS should tell prospective visitors the truth about their illness, even though it's not possible for a casual visitor to contract it; Teenagers are just as susceptible to AIDS as adults; A person can have the AIDS virus without knowing it or infect a partner; Insects don't transmit AIDS; and Your own blood is the safest blood you can receive during transfusion. These are some of the facts the general public wants to hear.

Another tragic risk group are the children born with AIDS. About one-third of the children born with AIDS are orphaned or abandoned at birth, and some die without leaving the hospital because foster or adoptive parents cannot be found in time. There are in excess of 500 children with AIDS in the U.S.

A group home for AIDS infected children in Southern Alabama has been opposed by local residents. They fear the home would spread AIDS, bring vandalism, drug use or other crimes as well as a drop in property values.

Not only are some children born with AIDS but some develop it because they have hemophilia. Another group of innocent victims!

My only experience with a hemophiliac occurred 25 years ago. Danny, an eight year old, was in my classroom. His mother explained his need for immediate attention should he start bleeding. I understood enough about the disease to pay special attention to Danny when he was on the playground. My thoughts recently have been of Danny and wonder how the furor over AIDS has affected his life.

Twenty-five years ago the hemophiliac's greatest threat was bleeding to death. Today the threat of acquiring AIDS is just as frightening.

Many of the 200,000 hemophiliacs have severe conditions and frequently require fresh blood. Therein lies the problem. Is it possible to have a 100% AIDS-free blood supply?

In the last few years situations have sprung up around the country involving AIDS infecting hemophiliacs. Young boys who would not qualify as high risk groups such as homosexuals or IV drug users have found themselves innocent victims of a deadly and greatly feared condition — the Acquired Immune Deficiency Syndrome.

The ideal way a community should react to this situation was recently reported by the news media. Todd White, an 18-year-old hemophiliac, who died recently of AIDS was allowed to stay in school and participate in activities with classmates until the final months of his life.

Todd's story provides a striking contrast to the experiences in other towns such as Kokomo, Indiana and Arcadia, Florida, when the presence of AIDS-infected students has provoked boycotts, prejudice and even violence.

School officials credit the doctors in the community of 18,000 with educating teachers, students and parents with accurate facts about AIDS. The results were acceptance and support of Todd and not "AIDS Hysteria."

Throughout history, the medical profession has been relied upon for support and guidance in times of severe health problems. The influenza epidemics early in this century and the prevaccine polio epidemics serve as dramatic reminders of this. Not since the advent of polio vaccines has there been a communicable disease that poses such a threat. Thus, it becomes essential that physicians willingly accept the challenges that now face them. This challenge is to provide information, education, and where appropriate, treatment to an anxious public.

Studies have shown that it is very normal for health workers themselves to fear caring for AIDS patients. But only a minority have refused to treat them. AMA guidelines permit a physician to refuse to take an AIDS case, especially if the practitioner believes he or she isn't qualified to provide adequate care.

Another aspect of AIDS that involves the physicians is the new definition of AIDS that went into effect in September that will swell the number of AIDS cases by 10 to 15 percent. "Presumptively" AIDS, "AIDS-like" and "suspect" cases will now be reported as AIDS.

Physicians have not reported all cases in the past for fear of violating patient-doctor confidentiality, fear of a lawsuit or they just did not want to be involved.

Finally, in order to make the public aware of AIDS physicians must learn as much as possible about AIDS from medical publications, the AMA and the Center for Disease Control. It is the physician's responsibility to educate and counsel not only the individual patient, but the public in general.

A well-informed medical profession therefore is essential. The public expects — and deserves — the best information — and treatment available, and physicians must not shy away from meeting this responsibility.

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References: 1. Flomenbaum W. *Am J Cardiol* 57(2):38A-43A, 1986. 2. Broler DC, Fox WR, Chennovsin P. *J Clin Pharmacol* 21:599-603, 1981. 3. Iber FL, Baum RA. *J Clin Pharmacol* 21:697-700, 1981. 4. Henning R, Lundvall O. *Eur J Clin Pharmacol* 6:224-227, 1973. 5. Physicians' Desk Reference, 40th ed. Orel, NJ, Medical Economics Company, 1986, pp. 939, 1480. 6. Pentikainen PJ, et al. *Br J Clin Pharmacol* 4:39-44, 1977. 7. Losix. A Review. Somerville, NJ, Hoechst-Roussel Pharmaceuticals, Inc., 1980.

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INDICATIONS AND USAGE: Edema associated with congestive heart failure, hepatic and renal disease, including the nephrotic syndrome.

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CONTRAINDICATIONS: Anuria. Hypersensitivity and in patients in hepatic coma or in states of severe electrolyte depletion. Although Bumex can be used to induce diuresis in renal insufficiency, any marked increase in blood urea nitrogen or creatinine, or the development of oliguria during therapy of patients with progressive renal disease, is an indication for discontinuation of treatment.

WARNINGS: Dose should be adjusted to patient's needs. Excessive doses or too frequent administration can lead to profound water loss, electrolyte depletion, dehydration, reduction in blood volume and circulatory collapse with the possibility of vascular thrombosis and embolism, particularly in elderly patients.

Prevention of hypokalemia requires particular attention in patients receiving digitalis and diuretics for congestive heart failure, hepatic cirrhosis and ascites, states of aldosterone excess with normal renal function, potassium-losing nephropathy, certain diarrheal states, or other states where hypokalemia is thought to represent particular added risk to the patients.

In patients with hepatic cirrhosis and ascites, sudden alterations of electrolyte balance may precipitate hepatic encephalopathy and coma. Treatment in such patients is best initiated in the hospital with small doses and careful monitoring of the patient's clinical status and electrolyte balance. Supplemental potassium and/or spironolactone may prevent hypokalemia and metabolic alkalosis in these patients. In cats, dogs and guinea pigs, Bumex has been shown to produce ototoxicity. Since Bumex is about 40 to 60 times as potent as furosemide, it is anticipated that blood levels necessary to produce ototoxicity will rarely be achieved. The potential for ototoxicity increases with intravenous therapy, especially at high doses.

Patients allergic to sulfonamides may show hypersensitivity to Bumex.

PRECAUTIONS: Measure serum potassium periodically and add potassium supplements or potassium-sparing diuretics, if necessary. Periodic determinations of other electrolytes are advised in patients treated with high doses or for prolonged periods, particularly in those on low salt diets.

Hyperuricemia may occur. Reversible elevations of the BUN and creatinine may occur, especially with dehydration and in patients with renal insufficiency. Bumex may increase urinary calcium excretion. Possibility of effect on glucose metabolism exists. Periodic determinations of blood sugar should be done, particularly in patients with diabetes or suspected latent diabetes.

Patients should be observed regularly for possible occurrence of blood dyscrasias, liver damage or idiosyncratic reactions.

Especially in presence of impaired renal function, use of parenterally administered Bumex should be avoided in patients to whom aminoglycoside antibiotics are also being given, except in life-threatening conditions.

Drugs with nephrotoxic potential and bumetanide should not be administered simultaneously.

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Probenecid should not be administered concurrently with Bumex.

Concurrent therapy with indomethacin not recommended.

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Pregnancy: Bumex should be given to a pregnant woman only if the potential benefit justifies the potential risk to the fetus.

Bumetanide may be excreted in breast milk.

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ADVERSE REACTIONS: Muscle cramps, dizziness, hypotension, headache and nausea, and encephalopathy (in patients with preexisting liver disease).

Less frequent clinical adverse reactions are weakness, impaired hearing, rash, pruritus, hives, electrocardiogram changes, abdominal pain, arthritic pain, musculoskeletal pain and vomiting.

Other clinical adverse reactions are vertigo, chest pain, ear discomfort, fatigue, dehydration, sweating, hyperventilation, dry mouth, upset stomach, renal failure, asterixis, itching, nipple tenderness, diarrhea, premature ejaculation and difficulty maintaining an erection.

Laboratory abnormalities reported are hyperuricemia, azotemia, hyperglycemia, increased serum creatinine, hypochloremia, hypokalemia, hyponatremia, and variations in CO₂ content, bicarbonate, phosphorus and calcium.

Although manifestations of the pharmacologic action of Bumex, these conditions may become more pronounced by intensive therapy.

Diuresis induced by Bumex may also rarely be accompanied by changes in LDH, total serum bilirubin, serum proteins, SGOT, SGPT, alkaline phosphatase, cholesterol, creatinine clearance, deviations in hemoglobin, prothrombin time, hematocrit, platelet counts and differential counts. Increases in urinary glucose and urinary protein have also been seen.

DOSAGE AND ADMINISTRATION:

Oral Administration: The usual total daily dosage is 0.5 to 2.0 mg and in most patients is given as a single dose.

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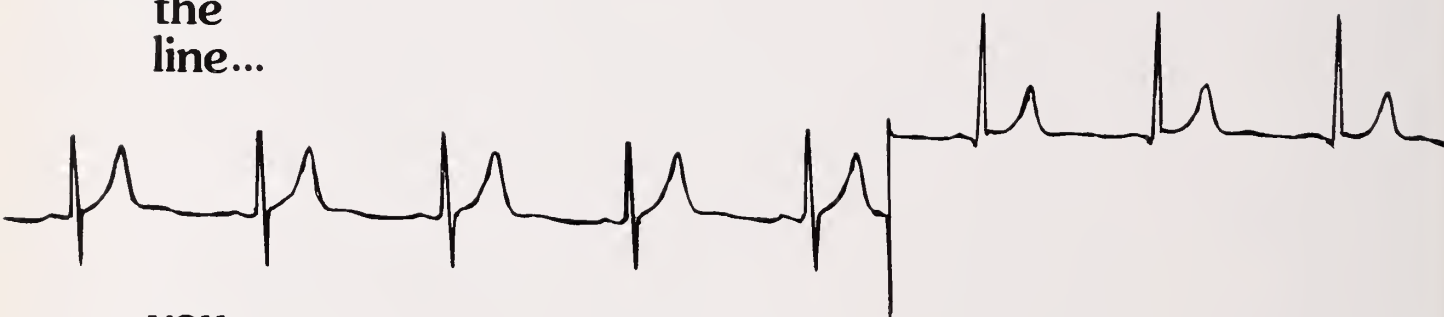
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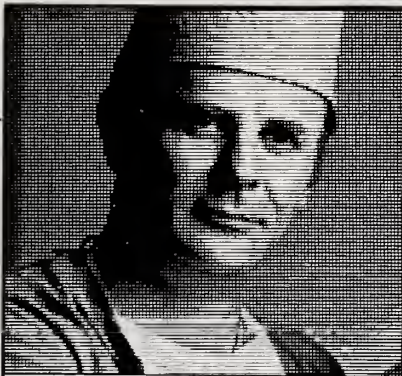
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Cover

Alabama woodlands in winter: monochrome from a charcoal sketch by Kimberly Anne Starr, Montgomery. Ms. Starr, in charge of Advertising and Design for *Alabama Medicine*, is a recent graduate (Psychology and Studio Art) of the University of Alabama.

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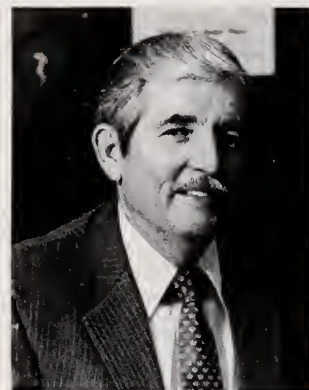
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Annus Mirabilis

The year 1666 was a mixed bag for the British. That was the year of the devastating great fire of London, but it was also the year of the important British victories over their tormentors, the Dutch.

The English laureate John Dryden celebrated the two events, a triumph and a tragedy, in a long 1667 poem titled *Annus Mirabilis*, year of wonders. When used today, *annus mirabilis* thus means any year of strikingly high contrast between good news and bad news, and the tension between these opposites.

For Alabama physicians, the year now ending was such a time — the *annus mirabilis* that saw, on the one hand, continued evidence of the heavy-handed attempts by public and private sectors to reduce the delivery of medical care to the lowest common denominator of cost and quality. On the other hand, your Association triumphed in two head-on engagements with forces that threatened your practice freedom and independent medical judgment.

Annus mirabilis 1987 brought you tort reform, after a long and difficult two-year struggle when no one could predict the outcome. And, months later, the Board of Censors persuaded Blue Cross/Blue Shield of Alabama to moderate the egregious PMD Amendment No. 2, which had outraged physicians the length and breadth of the state.

In both campaigns, tort reform and amendment reform, the leadership of the Association achieved what it did by high-minded persuasion, by building cases of irrefutable logic to support the cause of Alabama physicians and their patients, both before the Legislature and before the Blues.

Your leaders did not stoop to conquer. They rode tall in the saddle, sustained by the simple conviction that their position was right and that the overriding concern in both instances was the welfare of patients.

In the cockpit of politics and attempts to regiment medicine, right does not prevail simply on the strength

of its own righteousness. That may happen in Hollywood or on the tube, but in the real world right often goes begging, unless it is driven by organization, determination, and unity of purpose.

Both battles were sweaty but never dirty. The fact that physicians are encumbered by their lofty positions of prestige and public responsibility may be seen by some as a handicap. It is, but only in the limited sense physicians must work harder to prevail than those who prefer the back-alley approach.

In the end, medicine always comes out much better for having taken the high road of logic and persuasion. There remains no moral debt to pay, nothing to return to haunt later. The high ground is longer and rockier, but when the journey is over, it's over.

No one can say with any assurance what 1988 holds for Alabama doctors, but I expect we will see more of the same challenges that have complicated your art and science in the past several years. With the experience of *annus mirabilis* 1987, your elected officers face the future with confidence that the Association will give a good account of itself without jeopardizing the name of medicine.

More than many of you perhaps, I know how well represented you have been by your leaders, with whom I join in wishing you the joys of the season and high hopes for 1988. □

Lon

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Foods that may help reduce the risk of gastrointestinal and respiratory tract cancer are cabbage, broccoli, brussels sprouts, kohlrabi, cauliflower.

Fruits, vegetables and whole-grain cereals such as oatmeal, bran and wheat may help lower the risk of colorectal cancer.

Foods high in fats, salt- or nitrite-cured foods such as ham, and fish and types of sausages smoked by traditional methods should be eaten in moderation.

Be moderate in consumption of alcohol also.

A good rule of thumb is cut down on fat and don't be fat. Weight reduction may lower cancer risk. Our 12-year study of nearly a million Americans uncovered high cancer risks particularly among people 40% or more overweight.

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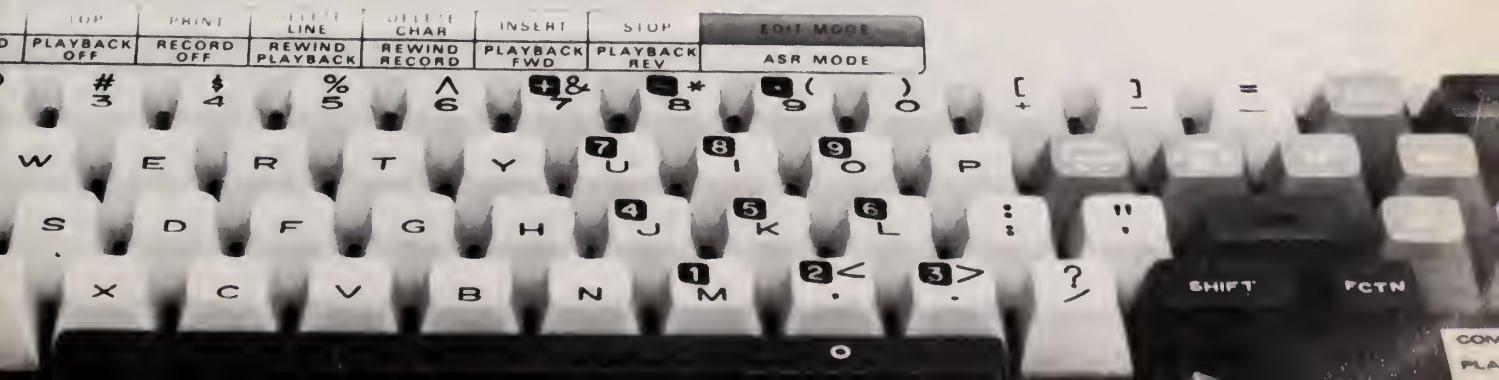
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PRESIDENT'S PAGE



Carl A. Grote, Jr., M.D.
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Musings At Year's End

Two-thirds of my year as your President is already gone. It has been an eventful time. In his column this month, Lon Conner sums up major happenings. For my part, I would like to pass on some impressions of the year, miscellaneous observations, and the like.

In a roomful of physicians in *any* discussion, the first few minutes will reveal as many different opinions as there are doctors present. After an hour or so, this divergence will be reduced by about half. And that is as close to a consensus as we are likely to get. I wouldn't have it any other way.

- Contrary to popular belief (a belief shared by a few physicians with no direct knowledge of medical leadership) your officers are no different. They argue, debate, and present anything but the cut and dried, predictable group-thought that some imagine.

- Some of the physicians most prone to finding fault with their chosen leaders are the least informed on current affairs. We're all short of time, but medicine needs an informed membership now more than ever before. And that requires constant homework. Read everything you can find on topics bearing on your profession in these troublesome times. *American Med-*

ical News is one good source, as are the commentaries in many specialty publications. And do not assume that because you understand an issue this week it will be the same next week. It won't be. The half-life of socioeconomic information in medicine is about five days now, and shrinking.

- More than a century ago, Ralph Waldo Emerson wrote: "These times of ours are serious and full of calamity, but all times are essentially alike." I believe that. The good old days of medicine weren't all that good. As I often say: "Today always looks worse than yesterday. And yesterday always looks better than when we were there."

- Prophets of gloom and doom are everywhere. They always have been. But in recent years medicine does seem to have had more than its share. Hand wringing and such laments as "all is lost" aren't going to get us anywhere. If our professional predecessors had given in to despair (and they had far more reason than we do today), where would we be?

- We cannot aim for the stars by looking at our feet. If we always plan for the road ahead, I believe the present will pretty much take care of itself. Vision can

best be described by the example of the man who plants a tree knowing he will never live to enjoy its shade. It was that kind of vision that brought the rewards that generations of physicians handed down to us. And it is that kind of vision we owe the future.

- When most of us answered the call to medicine, we knew it would be hard. We never expected a life of wine and roses. Why, then, are we so prone to complain of present difficulties? Maybe there are some physicians who were told that once in practice their worries would be over, but I don't know any.

- At bottom, much of clinical medicine is problem solving. If we bring that same spirit to our approach to political headaches and socioeconomic dilemmas, I believe that medicine will not only endure but will, as always, prevail.

I look forward to the unknown perils of 1988 with enthusiasm. I hope you do too. Any coach will tell you that confidence and optimism are more important keys to success than all the fancy plays in the world.

Best wishes for the holidays and the new year. ■

Carl

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Thoughts on Psychotherapy for Residents and Practitioners

Charles H. Smith, M.D.*

Abstract

The purposes of this paper are quickly outlined. Basically they are neither more nor less than implied in the title.

Some criteria for selection of patients suitable for psychotherapy are addressed. These will not be the same for each individual physician.

A few examples of errors in technique are presented for the readers' contemplation.

The phenomenon of transference is discussed. Both positive and potentially negative aspects are considered. In the same vein, our patients' growing sophistication and knowledge of psychological matters are felt to be food for thought.

Borrowing the currently popular Russian word *glasnost*, various aspects of communication are scrutinized.

The sociopathic individual is felt worthy of mention and is discussed with thoughts as to goals and limitations of therapy.

Although psychotropic drug therapy is felt to be outside the purpose of this paper, such therapy is briefly examined.

Introduction

Without intention to be dogmatic, the present paper is simply and summarily excluding the residents of and practitioners of psychiatry from consideration. By the end of residency, most psychiatrists have been exposed to sufficient schools of therapy to leave them confused for half a decade or more. A few never recover.

As the number of psychiatrists diminishes secondary to kwashiorkor, marasmus, beri beri, heat stroke, hypothermia and other poverty related diseases, some other physicians are going to have to assume the burdens of psychotherapy, like it or not.

Psychotherapy and pharmacotherapy, contrary to nearly everyone's wishes, are not synonymous. They are not even similar and the latter will never replace the former. Pharmacotherapy will be briefly addressed later on. Psychotherapy involves a give and take, an exchange of ideas and interpretations between patient and physician. Transactions of this sort are potentially damaging to the physician's ego and occasionally to his persona.

To Treat or Not to Treat?

It is evident that the physician is obligated to undertake emergency measures where such measures may

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Psychotherapy

continued from page 11

be life saving. The psychiatrist resuscitates or applies a tourniquet. The pathologist or radiologist attempts to dissuade a suicidal patient from jumping off a roof top. The matter of qualifications is not directly relevant. The word "doctor" still generally evokes a certain degree of respect as well as more attention than we might sometimes wish.

Beyond the mandatory life preserving measures, treatment (psychotherapy) necessarily becomes an individual choice. Despite the physician whose parents were alcoholics care or feel adequate to undertake care of a patient who is admitted to the hospital in a coma secondary to alcohol/drug ingestion? This is but one of many hard questions which might be posed. The physician may feel moved by the "sins" of the parents to obligate himself. Or he might be in revulsion of parental transgressions and make a quick referral. Either response seems, in human terms, easily understandable, but the pity is that either might be wrong. The doctor of rapid referral may be bypassing step one of "physician heal thyself." The accommodating physician may over identify with the patient and compound the patient's problems.

Hard questions have no easy answers. But there are clues, there are possibilities, actually old solutions, which we now ignore. We rush to the office early, leave late because we have to meet rising office expenses, liability and health insurance and reply to "peer reviews" which are more often than not invasions of our patients' privacy and a ruse to delay insurance payments than reviews of any scientific validity. So we find no time to consult experts. Those experts are our professional colleagues. We may delude ourselves by believing that we talk to our peers over lunch. And we do. We talk. We exchange no information pertaining to ourselves or our patients' problems. Noises are made, many of these noises may briefly address problem patients, not patients' problems. We have become far too cautious to admit any indecision on our own part and we are probably right. Talk continues but communication has never started. Which leaves us somewhere behind a dolphin.

A primary consideration in our determination to treat or refer is not very complex. Do we like the patient? Does the patient seem to like us? It is not impossible to treat a patient we dislike but it certainly complicates our situation and it should only rarely be necessary. Soul searching self analysis is not needed nor are masochistic ruminations. An old reliable, but often valid, rationalization is that while we like the patient, we just can't agree with what he/she is doing. This has particular merit when our patient clearly is more concerned with medication in ample supply than in looking into the need for medicine. Such patients quickly es-

cape our control and theirs. They will nearly always be well served by referral.

In summary, it will usually be in the best interest of the patient to refer when we feel an intuitive aversion or sense such an aversion on the part of the patient. This is true because we are neither more nor less than human. The writer has several patients who feel possessed of Divine authority but at this point in time the therapist seems destined to operate at a human level. Most would agree that it is noble to "love thy neighbor as thyself" but the same "most" may well have a neighbor whom he considers a jackass. Which only reminds us again of our humanity.

Technical Errors

Such errors are ubiquitous and in more learned hands could probably be made to constitute a book, a very boring book. But a few should be mentioned.

Most physicians feel an affection for children and prior to a psychotherapy session, however brief, may ask "Would you like to come into the office and talk for a while." This seems all very well but what if the child says "No"? Does one seize the child and force him/her into the office/playroom? If one does so, obviously rapport is shot and it is best to cancel the appointment for a week or so. If there is such a thing as an affectionately imperative tone, or vice versa, this tone would be the order of the day. Practically speaking, the child is instructed to enter the office, take the assigned chair and perform as directed. Harsh? No, the child is always a captive patient and as such, inclined to resistance.

The severely neurologically damaged patient is also captive and one never leaves the option to say "No." The same is true of the occasional person who may enter the office in chains and escorted by officers of the law. This person may come in for self-serving motives, e.g., Social Security Disability. But criminals are not very predictable.

Transference

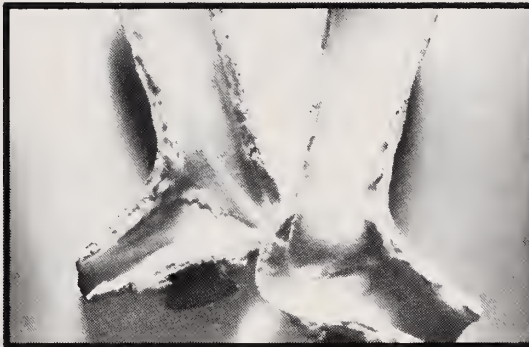
Charles Rycroft (*A Critical Dictionary of Psychoanalysis*) defines transference as "The process by which a patient displaces on to his analyst feelings, ideas, etc., which derive from previous figures in his life. . . ." This is not for Rycroft the end of the matter. His definitions proceed for a page and a half. Countertransference can be generally referred to as the same process in reverse.

It is difficult to imagine countertransference as resulting in anything but trouble. Regardless of analytic or other orientation, most will feel that the so called transference neurosis may be used through timely interpretation to the benefit of the patient.

The words "previous figures in his life" cover a lifetime. That lifetime includes the Oedipal period dur-

continued on page 14

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ing which the child may in fantasy view mother or father as love objects or destructive forces or, at a given time, one the lover, the other the aggressor. The physician who fails to recognize sexualized transference is in peril. The physician who recognizes the transference but chooses to ignore it in hope that it will go away is ill informed. The transference may in fact go away but only to be replaced by rage and compulsive need for revenge, particularly in the hysteroid patient.

One can offer no advice to the physician guaranteed to protect him from transference. He may be warm or distant, understanding or critical, prompt or tardy, but the parent to whom he is subject to identification may have had any of the qualities.

The physician would be well advised to recognize and deal with transference or at minimum suspect the phenomenon and deal himself out.

The Patient's Interpretations

We should understand that our patients of today are much more sophisticated in matters of psychology than they were a few years ago. Most of present day high school graduates will have written term papers on depression or similar encountered problems. Many college graduates will have taken several courses in psychology and some will be more conversant with neuroanatomy and neurophysiology than the physician. This is not to be seen as a threat to the treating person. Rather it should lead to quicker and closer collaboration between doctor and patient. Our somewhat older patients read magazine articles and watch television presentations on psychiatry. Many patients own the Physician's Desk Reference or various "pill books." It is unfortunate that many such books concentrate on stressing medication side effects while ignoring the beneficial effects for which they were marketed.

The total effect, though, of increased patient knowledge and sophistication should be a positive one. Doctors have, after all, been learning for years from the patients and there is no reason why psychotherapy should be an exception. If there were no patients, there could be no doctors and if there were no psychotherapy patients, there would be no psychotherapists.

Our patients' interpretation of their own behavior, thoughts and even dreams have become demanding of our respect. When the patient asks our interpretation of a given bit of behavior, he may well have his own preformed and well informed interpretation. Thus, the ancient psychiatric/psychological ploy of turning the question back upon the patient may assume greater value than it ever enjoyed at its time of origin. Again, one should emphasize that a modified egalitarian approach is not a shameful one. The patient will remain

aware that the physician has a much greater body of knowledge and it is not necessary to remind the patient that he is the patient. Or occasionally it may be very necessary. The physician operates under no oath to indefinitely tolerate a smart aleck and a rapid ego-puncture may be quite therapeutic for both.

What of our patients' dreams? Again, many are correctly interpreted by the patient and require little more than a nod of agreement. It has always seemed rather obvious to the writer that the patient is, with little guidance, the best interpreter of his own dreams and even when the interpretation is very evident, he has tended to insist upon patient interpretation.

But there are dreams and there are dreams. Some interpretations seem perfectly logical. Others seem a bit weird, not really conforming to what we may see as logic. They may prompt us to reevaluate the patient's mental status, to consider whether we may be overlooking an incipient psychosis. The writer has had in treatment for four years a now fifty year old chronic dysthymic female who has an occasional dream of water; rain water, lake water, it doesn't matter. She sees such dreams as premonitory of unfortunate consequences to her family or close friends, not necessarily lethal but of significant misfortune. To date she has not been wrong. She has a developmental history and certain personal characteristics, such as avoiding close interpersonal relationships, which might be consistent with an impression of Schizophrenia. But she is not Schizophrenic and at age fifty is not likely to develop an initial episode. She reports only dreams of water, not streams of dreams and she is batting 1,000. No explanation is even tentatively offered. No logic is discernable, but there it is. One cannot ask the patient to explain that for which she does not pretend to have an explanation. One can only respect Major League dreaming.

A Little More Glasnost?

There has got to be something ironic when a dictator representative of a system devoted to our destruction can preach with great success in Europe and considerable success in our own country, a patently phony policy.

This happens when our own physicians are looking forward, backward, from side to side for accusations of malpractice and usually know which attorneys to target. There is an obvious, but perhaps often overlooked, detrimental side effect. Few doctors are going to accept an attorney or his family as patients except in emergency situations. This currently is a minor health hazard but one which will grow rapidly in the absence of truly effective legislative relief; this has not really happened yet but it can't be terribly far away. Medical and Legal ethics dictate a care for those in need but as we perceive a legal notion that the only good doctor

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FOURTH INVITATIONAL SCIENTIFIC SYMPOSIUM

**Saturday, January 23, 1988 —
9 A.M. to 4 P.M.
Wynfrey Hotel, Birmingham**

- 8:30- 9:00 A.M. Registration — Coffee and Donuts
 Presiding — Elias G. Chalhub, M.D., Council on Medical Education
- 9:00- 9:25 A.M. James A. Whiteside, M.D.
 Traumatic Dislocation and Subluxation of the Patella in Athletes
- 9:25- 9:50 A.M. Carden Johnston, M.D.
 Intraosseous Infusions
- 9:50-10:10 A.M. Coffee Break
 Presiding — T. Riley Lumpkin, M.D., Council on Medical Education
- FOCUS ON CANCER**
- 10:10-10:30 A.M. Gary D. Monheit, M.D.
 The Epidemic of Skin Cancer
- 10:30-10:50 A.M. John Ferrar, M.D.
 Palpable and Nonpalpable Breast Lesions
- 10:50-11:10 A.M. Robert Y. Kim, M.D.
 Management of Cancer of the Uterine Cervix
- 11:10-11:30 A.M. J. Max Austin, M.D.
 Cancer Screening and GYN Oncology for the Practicing Physician
- 11:30-11:50 A.M. Panel discussion and questions on cancer papers moderated by Dr. Lumpkin
- 11:50- 1:00 Lunch — With Special Speaker Donald Williamson, M.D., Director of the Division
 of Disease Control
 Alabama Department of Public Health
 AIDS Update for Alabama
 Presiding — George M. Converse, M.D., Council on Medical Education
- 1:00- 1:25 P.M. Harold A. Helms, M.D.
 Epidemiology, Management and Outcome of Eye Trauma in Alabama
- 1:25- 1:50 P.M. James A. Kimble, M.D.
 Proven Laser Therapies for Eye Disease
- 1:50- 2:15 P.M. Robert L. Baldwin, M.D.
 Therapeutic Options in Treating the Dizzy Patient
- 2:15- 2:35 P.M. Coffee Break
 Presiding — J. Kirven Brantley, M.D., Council on Medical Education
- 2:35- 3:00 P.M. M. K. Oh, M.D.
 Sexually Transmitted Disease Among Adolescent Girls — Alabama Experience
- 3:00- 3:35 P.M. John L. Mathews, M.D.
 Mini Laparotomy and Cholecystectomy
- 3:25- 3:50 P.M. Terry A. Treadwell, M.D.
 The Foot in Diabetes Sugar Foot
- 4:00 P.M. Adjourn

Please enroll me in the Fourth Annual Invitational Scientific Symposium on Saturday, January 23, 1988 at the Wynfrey Hotel, Birmingham, Alabama. Enclosed is the registration fee of \$40, which includes lunch.

Name _____ Office Phone _____

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Specialty _____

Mail to: **MASA Education Department, P. O. Box 1900-C, Montgomery, AL 36197**

Psychotherapy

continued from page 14

is a sued doctor, we may unconsciously conclude that the only good lawyer is a deceased one. It is not conceivable that we would ever consciously make such a decision. It is too contrary to our learning, but we can't control our superego which, stoic as it is, will endure only so much abuse. This sounds cruel and if it ever happens it would be cruel beyond imagination. But because we are human, we do certain things outside our actual awareness. And because we remain human, we also do things of which we are perfectly aware. It would be of considerable interest to poll, in confidence, physicians as to how often they are booked up when an attorney calls for referral of self, family or client.

Glasnost, as it pertains to doctor/patient interchange, seems on the whole, to be going pretty well. Some physicians may be exploiting such things as Medicaid but they seem subject to fairly close scrutiny. Some patients will present with conscious intent to exploit the physician.

An actual case of such a patient intent seems useful. C. ———, a thirty-two year old white male, entered with a complaint of sexual urges toward two adolescent step-daughters. He professed a revulsion for such thoughts. He acknowledged a feeling of physical nausea upon reading of incestuous acts. He was drinking heavily owing to his distress but was working regularly. The potential therapist (in this case, the writer) asked what *should* be routine questions. In handwritten, as opposed to dictated, notes, the patient was asked about hallucinations, delusions, ideas of reference and the like. Comments were recorded that his affect was normal and associations were not loose. His ability to discern right from wrong was explored and recorded. He was seen fairly regularly. A large man of probably dull normal intelligence, he seemed to develop a sort of younger brother/older brother transference. After several months, he apologetically explained that he had been earlier indicted for Childhood Sexual Abuse and Sodomy and in a distant city was scheduled to face trial. Who had referred him? His lawyer. Thanking him for his referral, I wrote his legal representative and enclosed my initial notes. My testimony very quickly became undesirable.

To the misfortune of this patient, he had a dumb (but expensive) lawyer. The patient is probably now in prison. The lawyer's mistake was in referring him to a psychiatrist. What, and we are down to the punch line, might have happened if he were referred to an emergency room physician, a competent internist or a resident physician? This patient had somatic symptoms including chest pain which merited investigation. Well counseled, he should have been advised to present with physical complaints and without his psychological ones for a few visits. He, in his helplessness, had a certain

appeal and could have captured many physicians.

The above sounds like a rather scary story and it is. But it happened, it has happened before and it will again happen and it will happen to a substantial number of readers. The precautionary measures mentioned are not difficult or prolonged. Where legal or potentially legal matters are involved, a word to the wise should be sufficient.

Where glasnost may be falling somewhat short in doctor/patient relationships lies in our often stubborn refusal to admit error. This sort of refusal in a psychotherapeutic interchange is the antithesis of the ideal. Our patients need the awareness that we have made errors, do make errors and will continue to make errors. It is the writer's conviction that such awareness will not diminish the patient's respect for his therapist. Much to the contrary, a "neither of us is perfect" attitude seems an ideal way to begin a relationship. The resident should not be reluctant to admit inexperience, the patient is going to know anyway. It is indifference, not inexperience, which will alienate the patient and possibly render him dangerous. The depressed patient may be curious as to the number of suicides his physician has treated. Wouldn't you? In actual practice, the depressed person will usually lack the aggressiveness to pose the question directly. He is more apt to ask in general terms. He still deserves the best answer we can provide. According to a recent issue of an excellent journal, *Psychiatric Annals*, twenty percent of persons will suffer Major Depression and of that number, twenty percent will suicide. The writer's estimate is that in the Southeast, that figure would be appreciably lower because of the continued extended family, religious conviction that suicide is not within the realm of Divine acceptance, Celtic remnants of an ancestry which dictates that it is more fun to attack than retreat and probably other factors which, at the moment, don't come to mind.

The apparent lack of openness between physicians has been mentioned and need not be belabored. In the physician who has been sued, reticence is to be understood; in the remainder who have not, but expect to be, the same understanding prevails. There are no other doctors from whom to elicit an opinion.

Glasnost is a word which seems to have a certain fascination, which may account for its public appeal. One must wonder whether the person who embraces glasnost is a glasnostic. Is the student of glasnost a glasnostician? Would Alexander Pope have commented "A little glasnost is a dangerous thing, drink deep or taste not . . ." ? If Pope were alive today, that wise man may have said exactly that.

The Physician and the Sociopath

Many Sociopaths are in prison but more are not. No clinician is going to get through a career of practice

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Before prescribing, see complete prescribing information in SK&F CO. literature or PDR. The following is a brief summary.

*** WARNING**

This drug is not indicated for initial therapy of edema or hypertension. Edema or hypertension requires therapy titrated to the individual. If this combination represents the dosage so determined, its use may be more convenient in patient management. Treatment of hypertension and edema is not static, but must be reevaluated as conditions in each patient warrant.

Contraindications: Concomitant use with other potassium-sparing agents such as spironolactone or amiloride. Further use in anuria, progressive renal or hepatic dysfunction, hyperkalemia. Pre-existing elevated serum potassium. Hypersensitivity to either component or other sulfonamide-derived drugs.

Warnings: Do not use potassium supplements, dietary or otherwise, unless hypokalemia develops or dietary intake of potassium is markedly impaired. If supplementary potassium is needed, potassium tablets should not be used. Hyperkalemia can occur, and has been associated with cardiac irregularities. It is more likely in the severely ill, with urine volume less than one liter/day, the elderly and diabetics with suspected or confirmed renal insufficiency. Periodically, serum K⁺ levels should be determined. If hyperkalemia develops, substitute a thiazide alone, restrict K⁺ intake. Associated widened QRS complex or arrhythmia requires prompt additional therapy. Thiazides cross the placental barrier and appear in cord blood. Use in pregnancy requires weighing anticipated benefits against possible hazards, including fetal or neonatal jaundice, thrombocytopenia, other adverse reactions seen in adults. Thiazides appear and triamterene may appear in breast milk. If their use is essential, the patient should stop nursing. Adequate information on use in children is not available. Sensitivity reactions may occur in patients with or without a history of allergy or bronchial asthma. Possible exacerbation or activation of systemic lupus erythematosus has been reported with thiazide diuretics.

Precautions: The bioavailability of the hydrochlorothiazide component of 'Dyazide' is about 50% of the bioavailability of the single entity. Theoretically, a patient transferred from the single entities of triamterene and hydrochlorothiazide may show an increase in blood pressure or fluid retention. Similarly, it is also possible that the lesser hydrochlorothiazide bioavailability could lead to increased serum potassium levels. However, extensive clinical experience with 'Dyazide' suggests that these conditions have not been commonly observed in clinical practice. Angiotensin-converting enzyme (ACE) inhibitors can elevate serum potassium; use with caution with 'Dyazide'. Do periodic serum electrolyte determinations (particularly important in patients vomiting excessively or receiving parenteral fluids, and during concurrent use with amphotericin B or corticosteroids or corticotropin [ACTH]). Periodic BUN and serum creatinine determinations should be made, especially in the elderly, diabetics or those with suspected or confirmed renal insufficiency. Cumulative effects of the drug may develop in patients with impaired renal function. Thiazides should be used with caution in patients with impaired hepatic function. They can precipitate coma in patients with severe liver disease. Observe regularly for possible blood dyscrasias, liver damage, other idiosyncratic reactions. Blood dyscrasias have been reported in patients receiving triamterene, and leukopenia, thrombocytopenia, agranulocytosis, and aplastic and hemolytic anemia have been reported with thiazides. Thiazides may cause manifestation of latent diabetes mellitus. The effects of oral anticoagulants may be decreased when used concurrently with hydrochlorothiazide; dosage adjustments may be necessary. Clinically insignificant reductions in arterial responsiveness to norepinephrine have been reported. Thiazides have also been shown to increase the paralyzing effect of nondepolarizing muscle relaxants such as tubocurarine. Triamterene is a weak folic acid antagonist. Do periodic blood studies in cirrhotics with splenomegaly. Antihypertensive effects may be enhanced in post-sympathectomy patients. Use cautiously in surgical patients. Triamterene has been found in renal stones in association with the other usual calculus components. Therefore, 'Dyazide' should be used with caution in patients with histories of stone formation. A few occurrences of acute renal failure have been reported in patients on 'Dyazide' when treated with indomethacin. Therefore, caution is advised in administering nonsteroidal anti-inflammatory agents with 'Dyazide'. The following may occur: transient elevated BUN or creatinine or both, hyperglycemia and glycosuria (diabetic insulin requirements may be altered), hyperuricemia and gout, digitalis intoxication (in hypokalemia), decreasing alkali reserve with possible metabolic acidosis. 'Dyazide' interferes with fluorescent measurement of quinidine. Hypokalemia is uncommon with 'Dyazide', but should it develop, corrective measures should be taken such as potassium supplementation or increased dietary intake of potassium-rich foods. Corrective measures should be instituted cautiously and serum potassium levels determined. Discontinue corrective measures and 'Dyazide' should laboratory values reveal elevated serum potassium. Chloride deficit may occur as well as dilutional hyponatremia. Concurrent use with chlorpropamide may increase the risk of severe hyponatremia. Serum PBI levels may decrease without signs of thyroid disturbance. Calcium excretion is decreased by thiazides. 'Dyazide' should be withdrawn before conducting tests for parathyroid function. Thiazides may add to or potentiate the action of other antihypertensive drugs. Diuretics reduce renal clearance of lithium and increase the risk of lithium toxicity.

Adverse Reactions: Muscle cramps, weakness, dizziness, headache, dry mouth; anaphylaxis, rash, urticaria, photosensitivity, purpura, other dermatological conditions; nausea and vomiting, diarrhea, constipation, other gastrointestinal disturbances; postural hypotension (may be aggravated by alcohol, barbiturates, or narcotics). Necrotizing vasculitis, paresthesias, icterus, pancreatitis, xanthopsia and respiratory distress including pneumonitis and pulmonary edema, transient blurred vision, sialadenitis, and vertigo have occurred with thiazides alone. Triamterene has been found in renal stones in association with other usual calculus components. Rare incidents of acute interstitial nephritis have been reported. Impotence has been reported in a few patients on 'Dyazide', although a causal relationship has not been established.

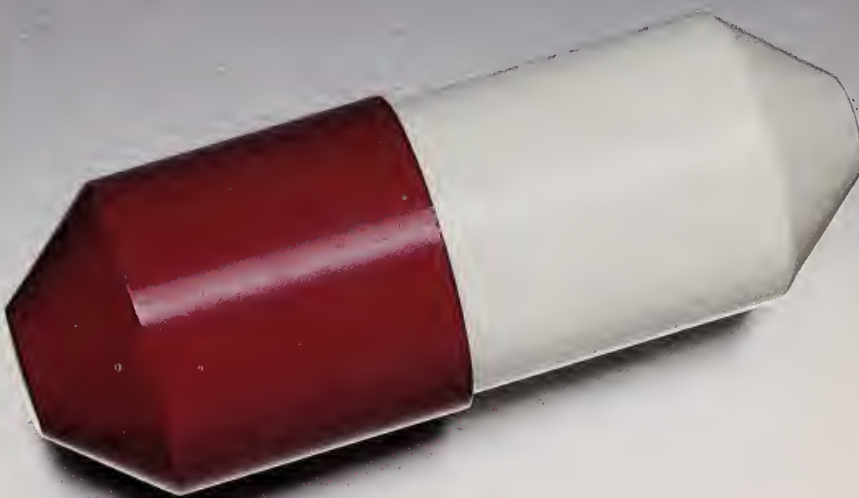
Supplied: 'Dyazide' is supplied as a red and white capsule, in bottles of 1000 capsules; Single Unit Packages (unit-dose) of 100 (intended for institutional use only); in Patient-Pak™ unit-of-use bottles of 100.

BRS-DZ L42

In Hypertension*... When You Need to Conserve K⁺

Remember the Unique Red and White Capsule: Your Assurance of SK&F Quality

Serum K⁺ and BUN should be checked periodically (see Warnings and Precautions).



Potassium-Sparing

DYAZIDE®

25 mg Hydrochlorothiazide/50 mg Triamterene/SKF

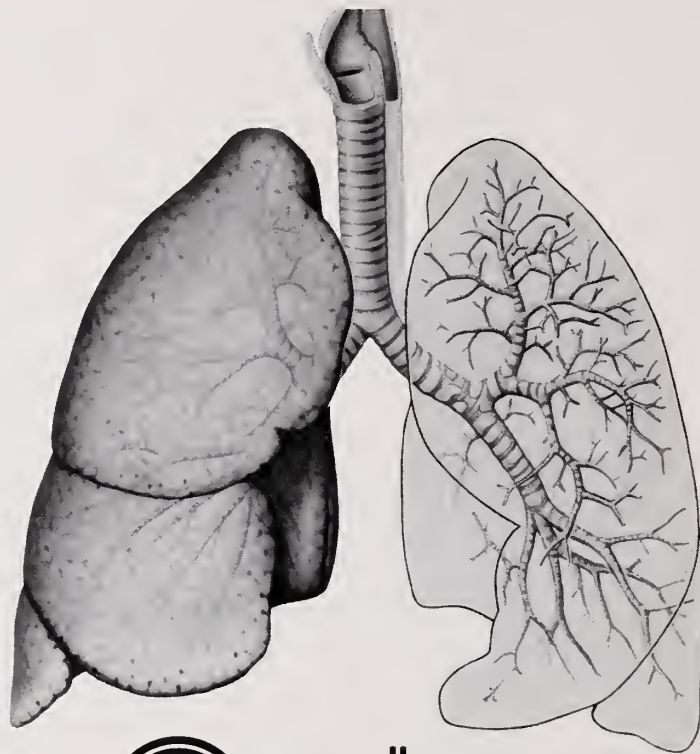
Over 20 Years of Confidence

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The unique
red and white
Dyazide® capsule:
Your assurance of
SK&F quality.



Consider the causative organisms...



Ceclor[®] cefactor

250-mg Pulvules[®] t.i.d.
offers effectiveness against
the major causes of bacterial bronchitis

Haemophilus influenzae and *Streptococcus pneumoniae*
(ampicillin-susceptible and ampicillin-resistant)

Note: Ceclor is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillin-allergic patients.

Ceclor[®] (cefactor)

Summary. Consult the package literature for prescribing information.

Indication: Lower respiratory infections, including pneumonia, caused by *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Streptococcus pyogenes* (group A β -hemolytic streptococci).

Contraindication:
Known allergy to cephalosporins.

Warnings:

CECLOR SHOULD BE ADMINISTERED CAUTIOUSLY TO PENICILLIN-SENSITIVE PATIENTS. PENICILLINS AND CEPHALOSPORINS SHOW PARTIAL CROSS-ALLERGENICITY. POSSIBLE REACTIONS INCLUDE ANAPHYLAXIS.

Administer cautiously to allergic patients. Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics. It must be considered in differential diagnosis of antibiotic-associated diarrhea. Colon flora is altered by broad-spectrum antibiotic treatment, possibly resulting in antibiotic-associated colitis.

Precautions:

- Discontinue Ceclor in the event of allergic reactions to it.
- Prolonged use may result in overgrowth of nonsusceptible organisms.
- Positive direct Coombs' tests have been reported during treatment with cephalosporins.
- Ceclor should be administered with caution in the presence of markedly impaired renal function. Although dosage adjustments in moderate to severe renal impairment are usually not required, careful clinical observation and laboratory studies should be made.
- Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.
- Safety and effectiveness have not been determined in pregnancy, lactation, and infants less than one month old. Ceclor penetrates mother's milk. Exercise caution in prescribing for these patients.

Adverse Reactions: (percentage of patients)
Therapy-related adverse reactions are uncommon. Those reported include:

- Gastrointestinal (mostly diarrhea): 2.5%.
- Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment.
- Hypersensitivity reactions (including morbilliform eruptions, pruritus, urticaria, and serum-sickness-like reactions that have included erythema multiforme [rarely, Stevens-Johnson syndrome] or the above skin manifestations accompanied by arthritis/arthritis and, frequently, fever): 1.5%; usually subside within a few days after cessation of therapy. Serum-sickness-like reactions have been reported more frequently in children than in adults and have usually occurred during or following a second course of therapy with Ceclor. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome.
- Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy.
- As with some penicillins and some other cephalosporins, transient hepatitis and cholestatic jaundice have been reported rarely.
- Rarely, reversible hyperactivity, nerv-

ousness, insomnia, confusion, hypertonia, dizziness, and somnolence have been reported.

- Other: eosinophilia, 2%; genital pruritus or vaginitis, less than 1%; and, rarely, thrombocytopenia.

Abnormalities in laboratory results of uncertain etiology

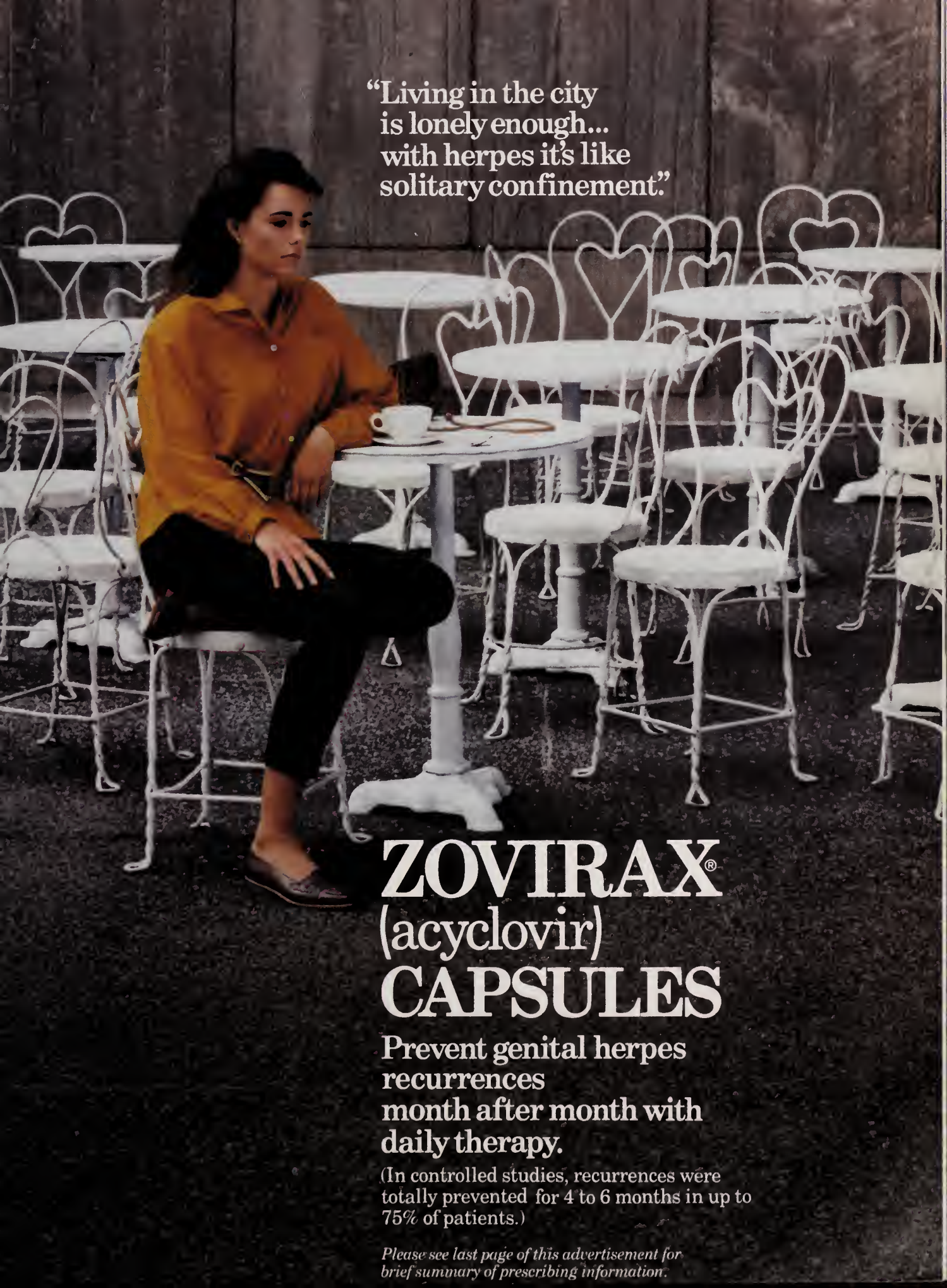
- Slight elevations in hepatic enzymes.
- Transient fluctuations in leukocyte count (especially in infants and children).
- Abnormal urinalysis; elevations in BUN or serum creatinine.
- Positive direct Coombs' test.
- False-positive tests for urinary glucose with Benedict's or Fehling's solution and Clinistix[®] tablets but not with Tes-Tape[®] (glucose enzymatic test strip, Lilly).

PA 0709 AMP

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Additional information available to the profession on request from Eli Lilly and Company, Indianapolis, Indiana 46285
Eli Lilly Industries, Inc.
Carolina, Puerto Rico 00630

A black and white photograph of a woman with dark hair, wearing a mustard-colored long-sleeved shirt and dark pants, sitting alone at a small round white table in a cafe. She is looking down with a somber expression. The cafe has many other similar white tables and chairs, all of which are empty. The background is a dark, textured wall.

**"Living in the city
is lonely enough...
with herpes it's like
solitary confinement."**

ZOVIRAX[®] **(acyclovir)** **CAPSULES**

**Prevent genital herpes
recurrences
month after month with
daily therapy.**

*(In controlled studies, recurrences were
totally prevented for 4 to 6 months in up to
75% of patients.)*

*Please see last page of this advertisement for
brief summary of prescribing information.*

ZOVIRAX[®] (acyclovir) CAPSULES

**Help free your
patients from
recurrences.**

Daily therapy

Coping with genital herpes is rarely easy. For some, the worst part is the pain and discomfort of frequent attacks — month after month, year after year. For others, the emotional burden presents a more difficult problem, leading to social isolation, anxiety, and diminished self-esteem.

Prevent or reduce recurrences

Although your patients have to live with herpes, they shouldn't have to suffer. Daily therapy with ZOVIRAX CAPSULES can help free them from the cycle of recurrent genital herpes. For many, one capsule three times a day can suppress recurrences completely while on therapy.

Generally well tolerated

Daily therapy with ZOVIRAX CAPSULES is generally well tolerated. The most frequent adverse reactions reported during clinical trials were headache, diarrhea, nausea/vomiting, vertigo, and arthralgia.

The physical and emotional difficulties posed by genital herpes are unique for each patient. The frequency and severity of recurrent episodes, as well as the emotional impact of the disease, should be considered when selecting daily therapy with ZOVIRAX CAPSULES.

*Please see brief summary of
prescribing information on next page.*



Prevent recurrences month after month*

ZOVIRAX[®]

(acyclovir) CAPSULES

Brief Summary

INDICATIONS AND USAGE: Zovirax Capsules are indicated for the treatment of initial episodes and the management of recurrent episodes of genital herpes in certain patients.

The severity of disease is variable depending upon the immune status of the patient, the frequency and duration of episodes, and the degree of cutaneous or systemic involvement. These factors should determine patient management, which may include symptomatic support and counseling only, or the institution of specific therapy. The physical, emotional and psycho-social difficulties posed by herpes infections as well as the degree of debilitation, particularly in immunocompromised patients, are unique for each patient, and the physician should determine therapeutic alternatives based on his or her understanding of the individual patient's needs. Thus Zovirax Capsules are not appropriate in treating all genital herpes infections. The following guidelines may be useful in weighing the benefit/risk considerations in specific disease categories:

First Episodes (primary and nonprimary infections — commonly known as initial genital herpes):

Double-blind, placebo-controlled studies have demonstrated that orally administered Zovirax significantly reduced the duration of acute infection (detection of virus in lesions by tissue culture) and lesion healing. The duration of pain and new lesion formation was decreased in some patient groups. The promptness of initiation of therapy and/or the patient's prior exposure to Herpes simplex virus may influence the degree of benefit from therapy. Patients with mild disease may derive less benefit than those with more severe episodes. In patients with extremely severe episodes, in which pruritus, central nervous system involvement, urinary retention or inability to take oral medication require hospitalization and more aggressive management, therapy may be best initiated with intravenous Zovirax.

Recurrent Episodes:

Double-blind, placebo-controlled studies in patients with frequent recurrences (6 or more episodes per year) have shown that Zovirax Capsules given for 4 to 6 months prevented or reduced the frequency and/or severity of recurrences in greater than 95% of patients. Clinical recurrences were prevented in 40 to 75% of patients. Some patients experienced increased severity of the first episode following cessation of therapy; the severity of subsequent episodes and the effect on the natural history of the disease are still under study.

The safety and efficacy of orally administered acyclovir in the suppression of frequent episodes of genital herpes have been established only for up to 6 months. Chronic suppressive therapy is most appropriate when, in the judgement of the physician, the benefits of such a regimen outweigh known or potential adverse effects. In general, Zovirax Capsules should not be used for the suppression of recurrent disease in mildly affected patients. Unanswered questions concerning the human relevance of *in vitro* mutagenicity studies and reproductive toxicity studies in animals given very high doses of acyclovir for short periods (see Carcinogenesis, Mutagenesis, Impairment of Fertility) should be borne in mind when designing long-term management for individual patients. Discussion of these issues with patients will provide them the opportunity to weigh the potential for toxicity against the severity of their disease. Thus, this regimen should be considered only for appropriate patients and only for six months until the results of ongoing studies allow a more precise evaluation of the benefit/risk assessment of prolonged therapy.

Limited studies have shown that there are certain patients for whom intermittent short-term treatment of recurrent episodes is effective. This approach may be more appropriate than a suppressive regimen in patients with infrequent recurrences.

Immunocompromised patients with recurrent herpes infections can be treated with either intermittent or chronic suppressive therapy. Clinically significant resistance, although rare, is more likely to be seen with prolonged or repeated therapy in severely immunocompromised patients with active lesions.

CONTRAINDICATIONS: Zovirax Capsules are contraindicated for patients who develop hypersensitivity or intolerance to the components of the formulation.

WARNINGS: Zovirax Capsules are intended for oral ingestion only.

PRECAUTIONS: General: Zovirax has caused decreased spermatogenesis at high doses in some animals and mutagenesis in some acute studies at high concentrations of drug (see PRECAUTIONS — Carcinogenesis, Mutagenesis, Impairment of Fertility). The recommended dosage and length of treatment should not be exceeded (see DOSAGE AND ADMINISTRATION).

Exposure of Herpes simplex isolates to acyclovir *in vitro* can lead to the emergence of less sensitive viruses. The possibility of the appearance of less sensitive viruses in man must be borne in mind when treating patients. The relationship between the *in vitro* sensitivity of Herpes simplex virus to acyclovir and clinical response to therapy has yet to be established.

Because of the possibility that less sensitive virus may be selected in patients who are receiving acyclovir, all patients should be advised to take particular care to avoid potential transmission of virus if active lesions are present while they are on therapy. In severely immunocompromised patients, the physician should be aware that prolonged or repeated courses of acyclovir may result in selection of resistant viruses which may not fully respond to continued acyclovir therapy.

Drug Interactions: Co-administration of probenecid with intravenous acyclovir has been shown to increase the mean half-life and the area under the concentration-time curve. Urinary excretion and renal clearance were correspondingly reduced.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Acyclovir was tested in lifetime bioassays in rats and mice at single daily doses of 50, 150 and 450 mg/kg given by gavage. There was no statistically significant difference in the incidence of tumors between treated and control animals, nor did acyclovir shorten the latency of tumors. In 2 *in vitro* cell transformation assays, used to provide preliminary assessment of potential oncogenicity in advance of these more definitive life-time bioassays in rodents, conflicting results were obtained. Acyclovir was positive at the highest dose used in one system and the resulting morphologically transformed cells formed tumors when inoculated into immunosuppressed, syngeneic, weanling mice. Acyclovir was negative in another transformation system considered less sensitive.

In acute studies, there was an increase, not statistically significant, in the incidence of chromosomal damage at maximum tolerated parental doses of 100 mg/kg acyclovir in rats but not Chinese hamsters; higher doses of 500 and 1000 mg/kg were clastogenic in Chinese hamsters. In addition, no activity was found after 5 days dosing in a dominant lethal study in mice. In 6 of 11 microbial and mammalian cell assays, no evidence of mutagenicity was observed. At 3 loci in a Chinese hamster ovary cell line, the results were inconclusive. In 2 mammalian cell assays (human lymphocytes and L5178Y mouse lymphoma cells *in vitro*), positive responses for mutagenicity and chromosomal damage occurred, but only at concentrations at least 400 times the acyclovir plasma levels achieved in man.

Acyclovir has not been shown to impair fertility or reproduction in mice (450 mg/kg/day, p.o.) or in rats (25 mg/kg/day, s.c.). At 50 mg/kg/day s.c. in the rat, there was a statistically significant increase in post-implantation loss, but no concomitant decrease in litter size. In female rabbits treated subcutaneously with acyclovir subsequent to mating, there was a statistically significant decrease in implantation efficiency but no concomitant decrease in litter size at a dose of 50 mg/kg/day. No effect upon implantation efficiency was observed when the same dose was administered intravenously. In a rat peri- and postnatal study at 50 mg/kg/day s.c., there was a statistically significant decrease in the group mean numbers of corpora lutea, total implantation sites and live fetuses in the F₁ generation. Although not statistically significant, there was also a dose related decrease in group mean numbers of live fetuses and implantation sites at 12.5 mg/kg/day and 25 mg/kg/day, s.c. The intravenous administration of 100 mg/kg/day, a dose known to cause obstructive nephropathy in rabbits, caused a significant increase in fetal resorptions and a corresponding decrease in litter size. However, at a

maximum tolerated intravenous dose of 50 mg/kg/day in rabbits, there were no drug-related reproductive effects.

Intraperitoneal doses of 320 or 80 mg/kg/day acyclovir given to rats for 1 and 6 months, respectively, caused testicular atrophy. Testicular atrophy was persistent through the 4-week postdose recovery phase after 320 mg/kg/day; some evidence of recovery of sperm production was evident 30 days post-dose. Intravenous doses of 100 and 200 mg/kg/day acyclovir given to dogs for 31 days caused aspermatogenesis. Testicles were normal in dogs given 50 mg/kg/day, i.v. for one month.

Pregnancy: Teratogenic Effects: Pregnancy Category C. Acyclovir was not teratogenic in the mouse (450 mg/kg/day, p.o.), rat (50 mg/kg/day, s.c.) or rabbit (50 mg/kg/day, s.c. and i.v.). There are no adequate and well-controlled studies in pregnant women. Acyclovir should not be used during pregnancy unless the potential benefit justifies the potential risk to the fetus. Although acyclovir was not teratogenic in animal studies, the drug's potential for causing chromosome breaks at high concentration should be taken into consideration in making this determination.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Zovirax is administered to a nursing woman. In nursing mothers, consideration should be given to not using acyclovir treatment or discontinuing breastfeeding.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS — Short-Term Administration: The most frequent adverse reactions reported during clinical trials were nausea and/or vomiting in 8 of 298 patient treatments (2.7%) and headache in 2 of 298 (0.6%). Less frequent adverse reactions, each of which occurred in 1 of 298 patient treatments (0.3%), included diarrhea, dizziness, anorexia, fatigue, edema, skin rash, leg pain, inguinal adenopathy, medication taste and sore throat.

Long-Term Administration: The most frequent adverse reactions reported in studies of daily therapy for 3 to 6 months were headache in 33 of 251 patients (13.1%), diarrhea in 22 of 251 (8.8%), nausea and/or vomiting in 20 of 251 (8.0%), vertigo in 9 of 251 (3.6%), and arthralgia in 9 of 251 (3.6%). Less frequent adverse reactions, each of which occurred in less than 3% of the 251 patients (see number of patients in parentheses), included skin rash (7), insomnia (4), fatigue (7), fever (4), palpitations (1), sore throat (2), superficial thrombophlebitis (1), muscle cramps (2), paronychia (1), menstrual abnormality (4), acne (3), lymphadenopathy (2), irritability (1), accelerated hair loss (1), and depression (1).

DOSAGE AND ADMINISTRATION: Treatment of initial genital herpes: One 200 mg capsule every 4 hours, while awake, for a total of 5 capsules daily for 10 days (total 50 capsules).

Chronic suppressive therapy for recurrent disease: One 200 mg capsule 3 times daily for up to 6 months. Some patients may require more drug, up to one 200 mg capsule 5 times daily for up to 6 months.

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Patients With Acute or Chronic Renal Impairment: One 200 mg capsule every 12 hours is recommended for patients with creatinine clearance ≤ 10 ml/min/1.73 m².

HOW SUPPLIED: Zovirax Capsules (blue, opaque) containing 200 mg acyclovir and printed with "Wellcome ZOVIRAX 200" - Bottles of 100 (NDC-0081-0991-55) and unit dose pack of 100 (NDC-0081-0991-56).

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*In controlled studies, recurrences were totally prevented for 4 to 6 months in up to 75% of patients.

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Psychotherapy

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without encountering his quota of Sociopaths. We may justly insist that one such person is more than our quota but it won't work. They are rather bountiful and they seem to reproduce in their own image.

Easily the most important thing to remember is that the Sociopath is potentially a very dangerous individual. We tend to think of him as impulse ridden and at times he may be. Also he is cunning, often brutal, conniving and, given appropriate stimulus, can delay gratification in service of what he conceives to be revenge. He may be an intelligent, even charming, conversationalist and hail fellow well met. He may seem a person you would like to get to know. Believe, he is not a person you would want to know beyond making an appropriate diagnosis.

For purposes of illustration, one might compare the manic psychotic with the Sociopath. The Manic is dangerous if his impulse of the moment is thwarted. If one is sufficiently fleet of foot or surrounded by sufficient male staff, one is safe and by the following day the whole matter is forgotten. If the Sociopath truly decides you belong among the dead, you should update your last Will and Testament. Or join the Navy. Or something.

Although it may be quite primitive, the Sociopath will usually have some sense of fair play and will appreciate a similar but stronger quality in his physician. What we have to offer him in terms of guidance is limited. The most mistaken thing we could try would be an effort to build for him a Superego. One cannot build without a foundation. We can teach him how to stay out of prison. He really doesn't want to be there and if we are persistent without becoming inflexible, he may appreciate our efforts and both patient and society will be beneficiaries. But we do not attempt an appeal to the conscience. The Sociopath neither has nor has any wish for one. This element of the psyche is a nuisance. We can be forgiven if we have an occasional pang of envy for that patient who is unencumbered by a conscience. "Sociopath for a Day" should be a popular television game show. While we can possibly teach the Sociopath to avoid prison, we will be unsuccessful in efforts to intrude upon his "personal life" which may include spouse and child abuse.

If our sociopathic patient likes us, we may be stuck with him. If he fervently dislikes us, we may be stuck in a literal sense.

It ought to be emphasized that the above discussion deals with the dyed in the wool no holds barred, red blooded American Sociopath. In contrast, we all have had patients who we are likely and sometimes fondly apt to refer to as Psychopaths or Sociopaths. These are patients who do have psychopathic deviant traits which will be reflected in psychological testing but can also be identified clinically. They like to see how

much they can bend the rules without breaking them or at least breaking them without getting caught. They are the manipulators without equal. They may become angry when we discourage manipulation. They see frustration of manipulation as a challenge, they regroup and try again. And yet again.

This large group of patients are not without a concept of right and wrong. Wrong just often seems more attractive. Many are alcohol prone. They are not brutal. They do not represent the physical threat present in the genuine article. They may be quite kind and empathetic, especially toward others with similar personality patterns. So we are discussing two different type persons who may bear the same label. This is not particularly tragic. It is tragic only if we are guilty of diagnostic error, an error which we cannot afford.


Historically it might be worthwhile to briefly trace the nomenclature of the Psychopath/Sociopath which many physicians may have read and wisely forgotten. It would seem imperative to give credit to such persons as Freud, Bleuler and the psychoanalytic thinkers for initial efforts toward a relatively orderly move directed to nomenclature. In the (analytic) beginning, certain disease entities were identified. We had Conversion Hysteria, Phobias, Obsessive Compulsives, etc. This left a large group of persons recognized as ill but without specific diagnoses and these were lumped together as Psychopaths. And so they remained for some time. Not really until this century was systematic attempt made to contribute substantially to the nomenclature. We have had DSM I, DSM II, and DSM III, and doubtless will in the future have DSM IV and so on. We may eventually equal the Super Bowl. The result has been to remove the "Psychopath" from the waste heap and replace him with the Sociopath who has specific personality patterns. The tendency to use Psychopath/Sociopath interchangeably has remained and is still fairly common.

Use of Psychotropic Medications

Psychotropics are still being investigated by research psychiatrists, psychologists and neuropsychologists. Until, and if ever, this process ends, the best advice one can give is to use them with respect. This is also the advice that will be ignored by a number of physicians, that number varying from most to all. The next best thing is not to screw things up too badly.

The depressed individual remains the most reliable model. That person, most often than not compulsive, may present with a list of medications that failed to work. He/she may inform the psychiatrist that perhaps one or two served as an aid to sleep but other than this didn't do much toward alleviating depression. The next thing the psychiatrist will ask is identification of the medicine, daily dosage and the length of trial on the "unsuccessful" antidepressant. Without deliber-

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ately singling out any given medication, one can say that, e.g., Imipramine and Amitriptyline are two old (and useful) drugs with which most clinicians are familiar and feel comfortable.

These same physicians will be aware of common side effects and impart this knowledge to the patient. Faced with a Major Depression, how many physicians are familiar with the necessary dosage and length of time of therapeutic effect of the two drugs just mentioned? They are roughly 150-300 mgm and four to six weeks, far less dosage and far shorter time than most patients will receive.

Many Dysthymic persons may respond to a 50 mgm bedtime dose of these antidepressants. But they are responding to their confidence in their physician and to that physician's reassurance and confidence in himself. They are, in other words, responding to psychotherapy.

There is what may seem a contradiction in the above paragraphs. Is this person writing to us that we, as physicians, are going to have to become psychotherapists but attempting to deny us the use of psychotropic agents? This is not the intention. The intent is a word of caution. In medical school we do not become well familiar with the whole spectrum of psychotropics. It seems best to become familiar with a smaller number of antidepressants, anxiolytic agents, etc., and become familiar with their effects and side effects. Psychiatric consultation, if only on a one time basis, will be available if needed as regards medications with which the physician may feel ill at ease.

The use of neuroleptic (antipsychotic) medications by non-psychiatric practitioners seems questionable because of side effects, all distressing and at least two (Tardive Dyskinesia and Neuroleptic Malignant Syndrome) very severe. Most psychiatrists would doubtless prefer that some other physician initiate neuroleptic therapy. But the psychotic patient has got to have antipsychotic medication and there is no escaping this.

There ought to be a better way to end a paper than with what sounds like doomsday prophecies and in truth, serious side effects are rare. Yet, what needs saying needs saying.

Odds and Addendums

One had ought to never reread what he or she has written. It is at best a self punitive practice and worthy of the late, unlamented Hungarian Count Masoch (as opposed to the Gabor sisters). What one sees is a hundred words/phrases which are needful of slight change. Or a hundred reasons why the whole thing should be consigned to a waste basket.

Regarding the present paper, it can be noted that

the word "psychotherapy" is used all too narrowly. Any word or deed calculated to better the condition of the patient is *de facto* psychotherapy. It may be termed reassurance, consultation, a scolding, a heart to heart discussion, it doesn't really matter so long as the intent is benign and the hoped for result is therapeutic.

The physician's obligation in crisis intervention seems clear cut but the example chosen may be overly simplified. People can and do jump off roof tops but for each of these, dozens are found unconscious on country roadsides. If they smell strongly of alcohol, it seems logical to assume that they have overindulged and passed out. We will palpate the skull for possible fracture, we will inspect nose and ears for blood, check equality of pupils, test limbs for rigidity, neck for stiffness, check for positive Oppenheim, Chaddock and Babinski, in short, do about everything we can do barehanded. We are not likely to be equipped with ophthalmoscope, otoscope and so on. We will not, however, have ruled out completely recent closed head injury or cerebral vascular accident. We will proceed to the nearest town and request that an ambulance be dispatched. By the time the ambulance arrives and transports the patient to the appropriate hospital and the patient examined, the clinical picture may have totally changed. Pupils may be unequal, rigidity present, pathological reflexes abundant. We may then wonder just how far the Good Samaritan law extends. We may rest uneasily assured that any town worth its salt will contain at least one attorney ready and willing to test the validity and extension of that law. Should this mean that the physician should bypass the roadside unconscious patient? Perhaps logically yes but in practice a definite "no"; physicians, sometimes to their misfortune, are not always logical creatures.

Beyond emergency measures, we would seem to have an option to treat or not to do so but we must take care to avoid patient abandonment. We may not have a right to stop treatment until we have expressed in writing or in the presence of reliable witnesses our willingness to assist the patient, within reasonable time limits, in search for another physician. The criteria for patient/doctor and doctor/patient selection do seem worthwhile. The same seems true for the admittedly incomplete mention of technical errors, with particular attention to children.

The fact of the patients' growing sophistication in subjects of psychological interest may be a bitter pill for the physician, especially the psychiatrist, to swallow but it seems a matter of fact and seems likely to become increasingly a matter of fact. We probably would do well to accept it, embrace it and in the most benign way, exploit it to the well being of the patient. We do have a choice. We can accept or we can all become analysts on the theory that we will then au-

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tomatically assume control, perhaps a mistaken theory in all but the most primitive of patients. Acceptance is not without peril. The depressed or incipiently psychotic patient may consult his PDR on a regular basis and request a change in medication before the initial one has opportunity to prove or disprove itself. We may choose to retain what we see as command and insist that the patient continue his original medication until its worth is established. In this case the patient, more likely than not, will play his game with another physician or another or another. Or, where no excess of controlled medications is involved, we might see fit to allow the patient to play his PDR game until that reference is exhausted and he seeks our advice, or that of another doctor. Whatever the circumstances and they need not involve medication maneuvers, our patient is probably going to present with better insight than a few years ago. If our psychotherapy sessions often tend to take on a more conversational tone as opposed to "me Chief, you Indian" than was formerly the case and if our patient emerges improved, who cares? Or for what selfish reason?

The current head-on collision between lawyers and doctors can only be viewed with sorrow. This seemingly at this time is commencing much in the financial favor of the lawyer. Any doctor can be sued but few can be bought. And who wants a doctor who can be bought? Doctors can exist without lawyers. Few lawyers and their families can long exist in good health without doctors. Newspapers and news magazines are preoccupied with AIDS. A legal community without medical care commands no headlines but perhaps it should and it soon may. There is, as yet, no cure for AIDS. Sound legal and medical minds should be able to cooperate and produce a cure for their own impending crisis. This crisis has been mostly and not at all subtly been included in the subsection on *glasnost*. If *glasnost* or "openness" operates as advertised, this discussion is precisely where it belongs.

The perils of dealing with the Sociopath needs some discussion and receives some. When one offers the physician little but the option of remaining alive and keeping his patient out of prison, accolades are not expected.

Essentially all that can be said about psychotropics in a paper not intended to deal with them is said. For all the impact these remarks are likely to generate, it probably belongs in the waste basket. Still a few might listen.

Conclusion

Of psychotherapy one might do worse than borrow from Edward Gibbon "The winds and waves are always on the side of the ablest navigators." ■

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CORRESPONDENCE

A Plea for a Return to the Past

Editor, *Alabama Medicine*:

It is unusual to hear a young physician extol the virtues of health care past, but in the area of obstetrical care in Alabama, it seems appropriate.

When I began my faculty career at the School of Primary Medical Care in Huntsville in 1983, there were approximately 150 family physicians delivering babies in Alabama.¹ Most were rural physicians performing cesarean sections when needed, and the remainder had working arrangements with local surgeons.

A regional obstetrical referral network, largely based in our state's medical school campuses, provided ready access to care for high risk deliveries. We had moved from the state with one of the worst perinatal mortality rate to one of the better in the southeast. The family physicians in small towns throughout Alabama provided primary care for mothers and babies (as well as the males in the family) whether they could pay or not.

As these physicians decided to wind down their practices and retire, our family practice residency programs provided eager, well-trained replacements. We had a system we could be proud of, and it seemed like an ideal time to go to one of our best residencies to help teach obstetrics to medical students and residents — and it was fun.

Somewhere in the last few years, something awful happened. Annual medical liability insurance premiums for these physicians went from around \$6,000 to about \$35,000. Doctors who felt in touch with the families in their areas began to be called into court by them. Some regional centers stopped accepting high risk transports, and more indigent patients came to small hospitals in labor without the benefit of prenatal care.

Rural family physicians were forced to deliver these high risk patients whom they had never met before, generating more suits. These physicians considered their options seriously, and many begrudgingly stopped providing obstetrical care. We now have about 30 family physicians delivering babies in private practice in Alabama.

Medical school graduates now in family practice residency programs saw the handwriting on the wall: "If I want to stay in Alabama, I can't deliver babies." It was difficult for training programs to maintain their interest in training family physicians to do obstetrics. Now to be eligible for liability insurance, the new graduate had to be competent in cesarean section, a

significant problem for some programs. The result was that very few of our family practice residency graduates provide obstetrical care, and those few who do are choosing to locate outside Alabama.

These are the roots of the maternal health care crisis in Alabama, in my opinion. The system that existed through most of 1986 was studied and reported as the Alabama Perinatal Outcome Project: A network of family physicians. The results show outstanding results from these small community hospitals.^{2, 3, 4, 5} It would be a major step forward for our state to return to such a system.

There is no simple solution to this problem. Family practice obstetrics must be made economically feasible again, and we must re-ignite the community spirit in all physicians. The regional referral network must be strengthened and we must renew our commitment to all future Alabamians by providing quality maternal care for all. The report of the committee on Human Resource Development of the Southern Growth Policies Board is mandatory reading for concerned citizens.⁶ This report states that the cycle of poverty and ineffective education that we strive to overcome is fueled by poor health, and nowhere is this more apparent than in the results of inadequate maternity care.

This issue is a real and present danger to our way of life in the South. I urge each person to become involved in his/her own sphere of influence to discuss options to seek a lasting solution. It is, I think, worth the effort.

WILLIAM J. CRUMP, M.D.
Huntsville, AL

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Barely Passing

Editor, *Alabama Medicine*:

This is written in response to an article, "Persistence," written by a "Ucello, M.D." in the September, 1987 issue.

I can't tell where he got the component "Press On" from. His first paragraph implies that it might be from reading *Today's Chiropractic*.

I have always wanted to know where the "Press On" article came from. Is that the source?

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The whole article is so poorly written that the best I could give the writer is 70, and that is a passing mark if I were grading papers.

Without causing too much insult to injury, tell "Dr. Ucello" he might be suffering from some stage of Alzheimer's and it would be wise if he voluntarily submitted to the Impaired Physician's Committee of MASA.

JAMES D. NETTLES, M.D.
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Spontaneous Relapse of Late Onset Group B Streptococcal Septicemia

Pamela B. Hudson, M.D.*
John R. Montgomery, M.D.*

Abstract

Spontaneous relapse of Group B streptococcal (GBS) infection is rare. We describe an infant with late onset GBS septicemia and subsequent spontaneous relapse. There was no evidence of occult focus of infection, inadequate treatment or tolerance of the organism to Penicillin. In the absence of the above conditions, true spontaneous relapse of GBS septicemia can be diagnosed. There is no published protocol for treatment in these rare cases. We describe our approach to the management of this problem.

Case Report

S.F. was a 4-pound-3-ounce product of a spontaneous vaginal delivery at 37½ weeks gestation. Physical exam at birth was consistent with IUGR. Her 7-day nursery course was uneventful. Post-discharge growth and development were appropriate until 11 weeks of age when she was admitted to our hospital for fever and irritability. Physical exam revealed an acutely ill child with a rectal temperature of 104° but failed to reveal a source of infection. WBC was 5,000 with 23% band forms. CSF and urine studies were normal as was the admission chest film. Intravenous Ampicillin and Gentamicin were begun. Blood cultures were positive at 24 hours and GBS was identified. Urine and CSF cultures were sterile. GBS septicemia in this patient was subsequently treated for 14 days with intravenous Penicillin G (200,000 units/kg/d). She became afebrile 12 hours after admission. Repeat blood cultures during treatment were sterile. Nasopharyngeal culture for GBS was negative. She was discharged 24 afebrile hours after discontinuation of Penicillin.

At 14 weeks of age (seven days after discharge) she was readmitted with fever and irritability. Her interim course had been uneventful until the day of admission. Physical exam was remarkable for a rectal temperature of 103° F, ill-appearance and an area of cellulitis in the right submandibular area. A palpable lymph node was noted beneath the indurated area. WBC was 11,900 with 33% band forms. Again, CSF and urine studies

Spontaneous relapse of Group B streptococcal (GBS) infection has been described in the literature but is uncommon. We describe an infant with late-onset GBS septicemia and subsequent relapse in whom no apparent explanation was uncovered for the recurrence. Our clinical dilemma involved choosing safe and reasonable management of the relapse in the absence of a published protocol.

* Pediatric Program, University of Alabama in Huntsville, School of Primary Medical Care, Huntsville, Alabama. Correspondence and reprint requests: Pamela B. Hudson, M.D., or John R. Montgomery, M.D., c/o Pediatric Program, Clinical Science Center, Room 205, School of Primary Medical Care — UAH, 201 Governors Drive, Huntsville, AL 35801. (Phone: 205-536-5511.)

were normal, as was chest x-ray. Gram stain and culture of the skin and lymph node aspirates failed to demonstrate an organism. Intravenous Ampicillin, Gentamicin, and Chloramphenicol were started. Blood cultures were positive at 24 hours and again GBS was isolated. CSF and urine cultures were sterile.

Further study of the organism showed it to be GBS type III that did not exhibit tolerance to Penicillin.* She was treated for 21 days with intravenous Penicillin G (300,000 units/kg/d) and Gentamicin (7.5 mg/kg/d). Bone scan, echocardiogram, CT of the head, ultrasound of the right submandibular region, and ESR were all normal. Serum immunoglobulin G was 175/mg/dl (normal for age, 430 ± 119).¹ The patient empirically received one dose of gamma globulin. Blood cultures during treatment, 24 hours after the last dose of antibiotic and one week after discharge were sterile. Nasopharyngeal and throat cultures of the child were negative for GBS.

Cervical culture of the child's mother and throat cultures of all immediate family members were negative for GBS. Sera from both the patient and her mother were demonstrated to be deficient in antibody to GBS type III.* The child has done well since discharge.

Discussion

GBS infections can be divided into two distinct clinical entities based on time of onset. Early onset GBS disease is almost always due to exposure of the infant to a colonized maternal genital tract prior to or during delivery. Onset of disease is within hours to days of birth (mean 24 hours). In these cases, the organism isolated in the infant is of the same type as that found in the mother's GI or GU tract. The types responsible for early onset disease are types I, II, or III with even distribution among the three types.²

Late onset disease occurs between 7 days of age and 3 months of age (mean 24d). Epidemiology of these infections is less clear. Asymptomatic colonization at birth with later infection is felt to be the most likely cause. Nosocomial transmission in the nursery has been implicated in late onset disease and is felt to be from infant to infant. Transmission is made more likely by poor hand-washing and high infant-to-staff ratio. Lastly, community-acquired infection has been postulated. A small percentage of infants who are culture negative for GBS at hospital discharge are found to be culture positive two weeks later.^{2, 3, 4}

As opposed to early onset disease, late onset infection is predominate caused by type III organisms.

Several explanations have been offered for this phenomenon. It has been proposed that type III possesses a special virulence for infants at this age. Viral upper respiratory illness is noted in about 20 to 30 per cent of infants with late onset disease. Viral infection may alter natural mucus membrane resistance to the type III organism allowing a portal of entry for the bacteria. Poor host antibody production to type III seems to be the rule among infants with late onset disease.²

Manifestations of late onset disease are predominantly of three types. Meningitis comprises 85 per cent of these infections. Bacteremia without focus and bone or joint infections are the next most demonstrated manifestations. Mortality is significantly less in late onset GBS infections (23 per cent) than in early onset disease (50 per cent).

Relapse of GBS disease occurs either during treatment or within a month after discharge (mean 12d). This disease entity has been reported in a small number of patients. Reasons for relapse in one series of ten cases included inadequate treatment, persistent occult focus of infection, and tolerance to Penicillin. Inadequate treatment was the most commonly noted cause of relapse in seven of ten cases summarized by Baker.²

Recommendations for treatment of recurrent GBS infection are not well delineated but generally involve high doses of Penicillin and/or combination therapy with Penicillin and an aminoglycoside.

The case presented here is demonstrative of late onset GBS septicemia with relapse. Several points bear further discussion. First, this case seems to have been a true spontaneous relapse. An exhaustive search for occult focus of infection was not productive. This child did present with cellulitis and adenitis, but cultures were sterile. The association of cellulitis/adenitis and GBS septicemia has been described.^{5, 6, 7} The patient clearly received adequate treatment for GBS septicemia with appropriate doses of an antibiotic shown to be effective against the organism. As noted in other instances of relapsing GBS disease, the child's serum was deficient in antibody to GBS type III even after two bouts of septicemia. Interestingly, the mother's serum was also deficient in antibody to type III.

Secondly, our choice of antibiotics, their dosage, and duration of therapy for the relapse bears comment. Triple antibiotic therapy was our initial choice for septicemia of uncertain etiology. After cultures demonstrated GBS, Penicillin G 300,000 units/kg/d and Gentamicin 7.5 mg/kg/d were instituted since increased effectiveness against GBS has been noted with these two agents in combination.² Duration of therapy was arbitrarily chosen at 21 days as no published recommendations are available for the therapy of spontaneous relapse.

Finally, our approach to follow-up should be noted. Blood cultures were obtained during treatment, 24 hours

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* Typing, tolerance and antibody studies were performed under the direction of Dr. Carol J. Baker, Pediatric Infectious Disease Section, Baylor College of Medicine.

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Streptococcal Septicemia

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after the last dose of antibiotics and a final set of cultures was obtained one week after discharge. Nasopharyngeal culture of the child was negative. Rifampin has been used to eradicate persistent nasopharyngeal carriage of the organism. However, since neither the child nor her family has positive nasopharyngeal cultures, Rifampin therapy did not seem to be warranted.

Conclusion

Spontaneous relapse of GBS septicemia is uncommon but occurs in community-based pediatric practice. Guidelines for work-up, treatment and follow-up are not well delineated. An extensive search for an occult focus is imperative and should include a thorough physical examination and appropriate cultures. Computerized tomography of the head, echocardiogram, chest x-ray, bone scan, and other tests may be indicated depending on results of the initial work-up.

Optimal dose and duration of Penicillin for spontaneous relapse has not been published. Our approach

was to use Penicillin in high doses in combination with Gentamicin to take advantage of synergism between these two agents against GBS. In addition, we lengthened the course of therapy to three weeks.

Finally, follow-up protocol for relapsed infections is important. Our approach may have been excessive. We considered long-term oral Penicillin therapy, empiric Rifampin treatment, and weekly blood cultures but finally decided on a single set of negative blood cultures obtained one week after discharge. ■

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The Stress of Malpractice Litigation

The possibility of being sued for professional liability is a reality for physicians today. Medical families must be aware of the implications of this fact in their lives. We must be prepared with some knowledge of the issues involved and possible results on the lives of our families. Both the AMA and MASA and their auxiliaries have addressed this problem in recent years.

Professional liability first became a major issue for physicians in the 1930s. During that decade, claims began to materialize in significant numbers with the birth of modern medicine and its sophisticated technology. Those claims continued in significant numbers until World War II. Following the war, the issue began to surface again and in the 1960s, the number of claims increased substantially. By the 1970s, as claims continued to increase and liability insurance became more difficult to obtain, the problem was considered to be

of crisis proportions. Since that time, except for a brief respite in the late 1970s, the problem has continued to grow.

Many factors have combined to make professional liability a problem today. A major contributing factor is inflated and unrealistic patient expectations. Others are increased patient awareness, improved quality and competence of plaintiffs' attorneys, and the difficulty of assuring effective discipline and peer review. Physicians are better trained than ever before and practice a higher quality of medicine, a fact reflected in lower mortality rates and longer life spans for Americans.

When a professional liability suit is filed against a physician, it is tremendously stressful. It affects them professionally — they may doubt their competence, they may not be able to concentrate, they may not be confident in making decisions.

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I recently heard Dr. Erwin T. Janssen of the Menninger Foundation speak on the issue of "Family Stress During Malpractice Litigation." He outlined the responses of both physician and spouse during malpractice stress.

What is the stress like and what can be expected by the physician? Responses include anger, bitterness, shame, embarrassment, withdrawal from others. The physician often has a sense of diminished self-esteem and increasing self doubt. In the hospital setting there is decreased sense of professional competence and inhibitions in practice style and performance. They become suspicious of what others think of them and sense others would see them as a "bad doctor."

There is understandable anxiety caused by the uncertainty and ignorance of the legal process. There is also worry about what this would mean to family reputation and finances. Some have even wondered if their children would be able to finish college. Litigation has become the occupied centralogy in their lives evidenced by avoiding the doctors' lounge, decreased sexual interest and suicidal thoughts.

In many cases the physician chooses to suffer in silence in an attempt to protect his or her family. However the spouses can perceive the silence as abandonment. There seems to be reluctance of physicians to reach out for support.

Spouses of physicians pending litigation often perceive the suit as an open attack in public or professional and personal integrity of a loved one. They sometimes feel a sense of rejection by the physician and observe a temporary regression.

If this isn't bad enough the whole family must go through the public nature of a trial and the uncertainty and shame in public resulting in their own social withdrawal in the community.

The issues involved include the personalities of those involved, including the lawyers, the setting of litigation and the psychological factors.

Physicians tend to be both sensitive and passive. On the negative side of the coin they are pessimistic and have self doubt. However they have a strong desire to be thorough in their clinical work, have an exaggerated sense of responsibility, hope to be omnipotent

as well as a need to be loved and admired.

It is the desire of physicians to make no mistakes. Society expects perfection from them and they expect it from themselves.

The personalities of lawyers, on the other hand, tends to be reflected in their "business as usual" attitude. After all, they deal with litigation suits on a regular basis. They are surprised at how personally physicians react to being sued.

Another aspect involved in litigation is the courtroom setting. There is cultural shock for the physician moving from a "caring" situation into a "facts and figures" style of courtroom drama. There is a tremendous difference in the public nature of litigation and the private nature of clinical practice. It is difficult to move from a proactive care giver to the role of reactive defender. It is difficult to remember that being sued for malpractice is not necessarily related to "bad medicine."

One of the hardest issues to deal with during time of litigation is psychological in nature. There is a natural tendency toward self-analysis and soul searching. Physicians tend to withdraw and despair is often the result.

In short, it is a devastating event in physicians' lives. And because it affects them so personally, it also affects their spouses and families.

Many medical auxiliaries are providing a great service by developing support mechanisms for members whose spouses are faced with professional liability litigation. Some have begun support groups; others have established telephone hotlines. Whatever the mechanism, local auxiliaries can be involved in getting physicians' families through this difficult period by providing peer support, as well as an outlet for personal feelings. More and more medical families are becoming aware of malpractice stress and are seeking ways to help those in need. □

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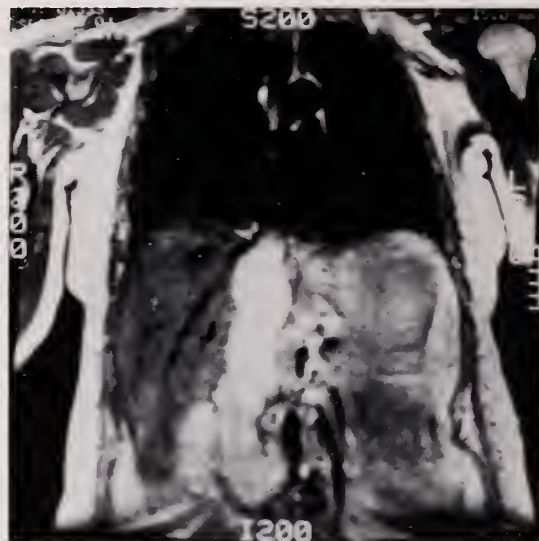
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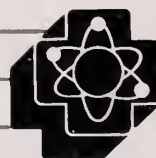


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OXYCODONE	XX	XX	XX	XX	XX

Blank space indicates that no such activity has been reported.

Table adapted from Facts and Comparisons (Nov.) 1984 and Catalano RB. The medical approach to management of pain caused by cancer. "Semin Oncol" 1975, 2; 379-92 and Reuler JB, et. al. The chronic pain syndrome: misconceptions and management. "Ann Intern Med" 1980, 93, 588-96.

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PRECAUTIONS:

Special Risk Patients: VICODIN should be used with caution in elderly or debilitated patients and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, prostatic hypertrophy or urethral stricture.

Information For Patients: VICODIN, like all narcotics, may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery; patients should be cautioned accordingly.

Cough Reflex: Hydrocodone suppresses the cough reflex; caution should be exercised when VICODIN is used postoperatively and in patients with pulmonary disease.

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Revised, April 1982.

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1. Hopkinson JH III: *Curr Ther Res* 24: 503-516, 1978

2. Beaver, WT *Arch Intern Med*, 141:293-300, 1981.

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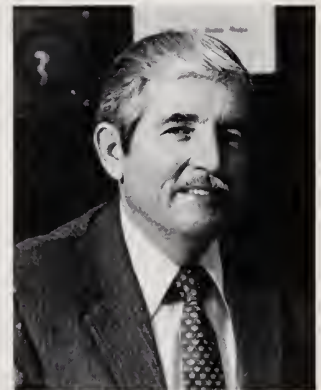
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Teenage Pregnancy

Alabama's infant mortality rate — a standard yardstick, nationally and internationally, of the health of a people — is No. 1 among the states and second only to the District of Columbia in this country.

Within the state the infant mortality rate (all figures are for 1986) ranges from a low of 1.6 infant deaths per 1,000 live births in St. Clair County to 26.4/1000 in Butler County. In 1986, the national average was 10.2.

A multidisciplinary effort is now underway to reduce this deplorable statistic, one that reflects on the state's good name in many ways, not the least being our attractiveness to new industry.

Putting aside the individual tragedies behind these numbers, the economic impact is awesome in a state with limited resources for public programs.

For every one of the 788 Alabama babies that died in 1986, many more were born with complications and disabilities requiring additional care, for which we all pay. The special education and long-term care of these handicapped children are estimated at almost \$38,000 per child per year.

Other cold facts:

- Studies show that for every dollar spent providing comprehensive care for high-risk women, \$3.38 may be saved in the treatment of low-birthweight babies.

- 149 women could receive prenatal care for the money it takes to treat five high-risk babies.

- The State of Virginia has determined that prenatal care could save \$59.8 million per year on care for the mentally retarded.

- The single factor most often associated with infant death in Alabama is low-birthweight. A low-birthweight baby is 40 times as likely to die during the first year of life as an average-weight baby, and twice as likely to suffer one or more handicaps in its lifetime.

- Alabama spends \$42 million per year on health care for low-birthweight babies.

- Largely because of the malpractice litigation history in Alabama, in more than a third of the counties of the state it is no longer possible for a woman to have her baby delivered by an obstetrician.

Summarizing these and other alarming statistics in his report to the Governor's Task Force on Infant Mor-

tality, State Health Officer Claude Earl Fox, M.D., said:

"The causes of Alabama's excessive infant death rate are multiple, and no one factor can be singled out as the major contributor. Our high incidence of teenage pregnancy, low-birthweight, poor education and poor economic status, lack of access for planned delivery services and medical care for infants and children, and delivery in a hospital neither equipped nor staffed for high-risk mothers and infants . . . all are major contributors."

Teenage pregnancies account for about one live birth in five in Alabama and a far higher percentage of infant death and long-term disability.

While work must proceed toward alleviating the infant death problem in the state, I believe that a heavier emphasis must be placed on *preventing pregnancy in the first place*.

Certainly, many of the state's teenage mothers didn't want children. One physician told me of seeing a 15-year-old mother with her third child, giving flesh and blood meaning to the national alarm over "children having children."

Alarmed over the Reagan Administration's proposal to eliminate the Family Planning Program in 1981, Former Health Officer Ira Myers, M.D., said this in an office interview with Bill McDonald and me six years ago:

"Every teenage pregnancy that occurs in this country costs the taxpayer about \$18,000 [higher than that today, of course]. We figure we prevented about 10,000 teenage pregnancies in Alabama through the Family Planning Program, that's \$180 million.

"About 13,000 got through. That's \$234 million we didn't save."

Without Family Planning Dr. Myers said then, the welfare program of the state would be devastated, along with Medicaid, public education, etc., "in a manner that would stagger the imagination."

Obviously, in today's world what is needed in Alabama is an increased emphasis on prevention of the very pregnancies that contribute so heavily to the infant mortality picture.

What Dr. Myers was saying (and with which Dr. Fox would emphatically agree) was that a jigger of prevention is worth a quart of cure.

He faulted both Medicare and Medicaid for approaching health care from the wrong end — the treatment end rather than the prevention end.

And he said he had come to the conclusion that curing illness (as, for example, relieving the infant mortality figure) is far more appealing to the public and to lawmakers than prevention. After all, he said then, illnesses that never occur do not make for much drama or popular support.

But prevention of unwanted pregnancy seems to me to be the imperative right now in the state's history.

When moral teaching fails, contraceptives and education must fill the gap to answer this problem.

I commend to the attention of Gov. Hunt and all the many committees and task forces looking at the state's infant mortality problem the poem that Dr. Myers always quoted verbatim in support of his belief (and mine) that prevention is the most economic and most humanitarian solution:

*"Twas a dangerous cliff, as they freely confessed,
Though to walk near its crest was so pleasant:
But over its terrible edge there had slipped
A duke and full many a peasant.
So the people said something would have to be done,
But their projects did not at all tally;
Some said, 'Put a fence around the edge of the cliff,'
Some, 'An ambulance down in the valley.'"*

*But the cry for the ambulance carried the day,
For it spread through the neighboring city;
A fence may be useful or not, it is true,
But each heart became brimful of pity
For those who "slipped over that dangerous cliff;
And the dwellers in highway and alley
Gave pounds or gave pence, not to put up a fence,
But an ambulance down in the valley."*

*Then an old sage remarked: 'It's a marvel to me
That people give far more attention
To repairing results than to stopping the cause,
When they'd much better aim at prevention.
Let us stop at its source all this mischief, cried he,
'Come, neighbors and friends, let us rally;
If the cliff we will fence we might almost dispense
With the ambulance down in the valley.'"*

*Better guide well the young than reclaim them when
old,
For the voice of true wisdom is calling,
'To rescue the fallen is good, but 'tis best
To prevent other people from falling.'
Better close up the source of temptation and crime
Than deliver from dungeon or galley;
Better put a strong fence round the top of the cliff
Than an ambulance down in the valley."*

The most cost-effective way for Alabama to leverage its limited resources to combat infant mortality is in fence-building, not ambulances at the bottom of the cliff. □

Lon

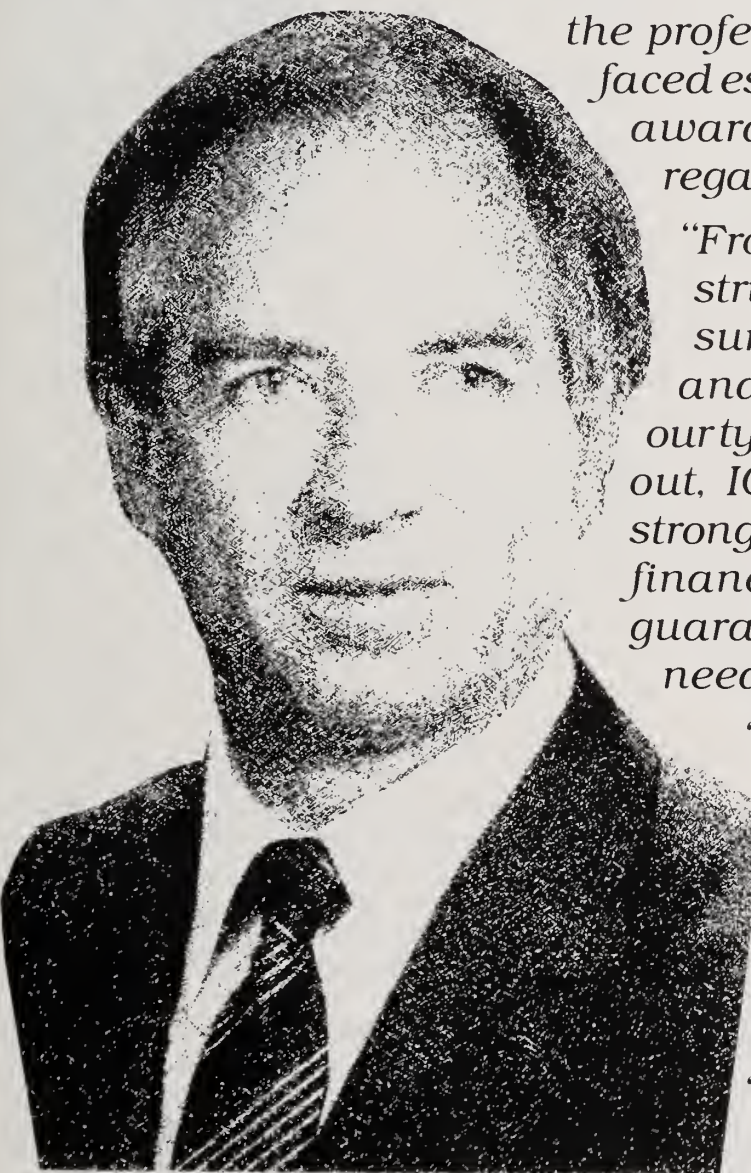
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PRESIDENT'S PAGE



*Carl A. Grote, Jr., M.D.
President, MASA*

Cold Water

In a recent survey of the membership of the Association, a majority of you expressed an interest in MASA's exploring the feasibility of establishing an independent practice association at the state level.

Your officers have been doing just that, exploring: the state delegation to the AMA interim meeting of the House of Delegates in Atlanta met with officers and staff of the Medical Association of Georgia in December to learn of their experiences in the IPA-HMO model they had undertaken.

Most of that news was less than encouraging: the Georgia HMO is giving up the ghost and the surviving IPA component had, at this writing, little more than hopeful contracts it might sign. It seemed to be a solution looking for a problem.

At the December meeting of the Board of Censors we listened as former MASA General Counsel John T. (Jack) Mooresmith (now specializing in health law in Mobile) described the complexities, mine fields and assorted tribulations of a statewide IPA. The risks of

such an organization, both in terms of federal law and economic exposure, are indeed formidable.

The Board had not opted to consider an insurance component (such as Georgia, to its sorrow, did with its HMO), assessing only the IPA element, seen as a magic way out of the market morass by some physicians.

Mr. Mooresmith carefully explained that it would be anything but easy. First of all, he repeatedly said, the organization could not be a sham — that is, a thinly disguised and limited effort to enjoy the privileges of collective action with only token economic and legal risk.

Applicable laws are stringent and searching, Mr. Mooresmith cautioned: to pass muster, an IPA would have to be a serious, all-out commitment to the complex and highly risky business as a genuine entry into the medical marketplace. For the IPA to survive, many physicians would have to invest not only substantial cash but thousands of man-hours of work and the le-

gally required risk must be unquestionably substantive. A token effort would be an inviting target for competing entities, which could bring actions under the antitrust laws for unfair market practices. So could consumers who felt they were somehow short-changed. Heavy damages could be assessed against individual members of the IPA so convicted.

As you know, the battlefield of alternative care systems is already littered with the wreckages of many an optimistic venture. It's brutal out there, Mr. Moore-smith warned. All these dangers and risks apply to locally structured IPAs, of course, but a state model would see an exponential expansion of the potential for disaster.

A paper organization, established simply to serve notice on carriers and others that the Association was arming itself, would have no deterrent effect on any market sector, Mr. Mooresmith said; neither would it have any practical value.

When you make the fateful step to get into this business, Mr. Mooresmith said, you must be prepared to take up all the headaches and hard work that go with the territory. Even then, given the casualty rate among such efforts, success would be a long-shot gamble.

Mr. Mooresmith's credentials to bring all this solemn news cannot be challenged: he has been actively engaged in the establishment of an IPA and has researched the law fully. He raised the question of what market niche the Association might aim for, and offered the suggestion that there may be no clearly defined role for a state IPA that could be discerned.

By implication, he was clearly saying that we would be launching a fragile ship into troubled waters.

I think it is fair to generalize the reaction of Board members to this elucidation as less than enthusiastic. We had little idea of the complexities of such a venture, nor of the scope of the legal and economic risks involved. That is why we have been assembling all the expert opinion we could find.

Mr. Mooresmith laid it all out for us to contemplate, warts and all, as we knew he would. While he might have an economic interest in the formation of such an entity, since his services would be invaluable, he was unsparing in pointing to the hazards, leaving it for us to decide whether the game would be worth the candle.

His candid presentation, added to our previous information from the Georgia experience, prompted a motion to table. It carried unanimously.

While the idea of a MASA IPA is not dead, it is very sick. Had those physicians who responded affirmatively to our survey seen all the negative evidence we have examined, I believe they would feel as most Board members do — this may be an idea whose time has gone, if there ever was such a time.

While we haven't closed the door entirely on the IPA concept, if everything remains as it is now such

ardor for the concept as might have existed is very diminished. If anyone has strong feelings, either way, on this subject, a good time to test their appeal would be at the district caucuses and, of course, at the annual session in April. □

Carl

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When the Federal Trade Commission opened the doors for advertising health services, the stage was set for fragmentation of our profession by subgroups established for self-protection.

Hospitals were first to inform the public about the services they offered. Later, hospitals, through individual marketing campaigns, became referral services for the doctors on their staffs. Then came PPOs, IPAs and HMOs. So, directly or indirectly, almost every physician in a large community is either marketing himself or being marketed by someone who has a vested interest in his patient clientele. Those involved in corporate health care know that control of patient flow is the key to successfully competing in the medical marketplace. That's why corporate entities are signing doctors to contracts.

While physicians spend 10-16 hours each day practicing medicine, administrators and corporate executives plot how they can control where and to whom patients go for medical services.

Is it any wonder that individual doctors feel compelled to market their services? Physicians are beginning to recognize the corporate and governmental conglomerates who are about to engulf us, while at the

same time, we see group-inspired fragmentation and shattering of the once valued professional code of ethics.

Public relations ‘‘wars’’ are fostered by individuals and specialty groups claiming to possess exclusive credentials and superior skills. These Madison Avenue Tactics are increasingly being embraced by the health care industry. Naturally, those who, by nature of an advertisement, are placed in a second-class status will retaliate with a public relations campaign of their own . . . and the PR battle is on. When one promoter proclaims to be the only authority on a subject, others competently performing the same services feel obliged to respond. The advertising agencies are licking their chops.

When a campaign of self-promotion offends a colleague or continues to either repress and degenerate a competing group, fuel is added to the fire. The natural response when backed into a corner is to retaliate in the name of survival. Professionalism then, slowly, but surely, yields to commercialism and, ultimately, fragmentation.

No one can disagree that our profession owes the

continued on page 15

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public the best health care in the world and that the public deserves to know about new advances in medicine. One of the reasons why ours has emerged as the standard by which all others are measured is because we have been allowed to practice within the free enterprise system. Competition engenders excellence; conversely, in our society, excellence is the cornerstone of success.

Inflated claims of special competence, however, offend colleagues and engender unrealistic expectations on the part of the public. Some professional societies would have us believe they are "protecting the public" from colleagues they have labeled as "less qualified." Physicians must not be misled by those advocating unlawful and/or anticompetitive activities. The status of "expert" is earned, not annointed. Often times, it is not clear who is being "protected," the public or the group proposing exclusivity.

For example, in the broad field of "plastic surgery," physicians and surgeons certified by several specialties are trained to perform both cosmetic and reconstructive procedures. The ophthalmologist is trained and board-certified to perform plastic and reconstructive surgery of the eyelids and orbit; the otolaryngologist, head and neck surgeon, is trained and board-certified to perform plastic and reconstructive surgery of the face, nose, head and neck; the dermatologist is trained and board-certified to perform many procedures considered to be "plastic surgery."

Reconstructive plastic surgery is also performed by orthopedists, neurosurgeons, urologists, general surgeons and others. Most of the craniofacial or orthognathic plastic and reconstructive surgery performed in the U.S. today is done by board-certified oral and maxillo-facial surgeons. General plastic surgeons are board-certified to perform plastic and reconstructive procedures over the entire body.

If any one of these groups should assume a position of aggression by virtue of a self-serving advertising campaign, naturally, those against whom the act is aimed would respond, and an intergroup conflict or "cold war" would result. Many specialty organizations have become too involved in protecting "turf."

Such activity lies at the very heart of our current dilemma: i.e., the fragmentation of our profession into sub-groups established for self-protection. Public disparagement of colleagues identified as competitors tends to denigrate the medical profession as a whole and places the architect of such activities in a risky position.

One of the examples of "unprofessional conduct" as defined by Alabama's Medical Licensure Commission is:

"Intentionally or knowingly making a false, deceptive or misleading statement in any advertisement or commercial solicitation for professional services and/or intentionally or knowingly make a false, deceptive or misleading statement about another physician or group of physicians in any advertisement or commercial solicitation for professional services. [Alabama code §34-24-360 (2)]"

Blatant disregard of this rule could subject a physician to disciplinary action by Alabama's Medical Licensure Commission, possibly resulting in revocation of his license.

How do we measure the skills claimed by those marketing professional services? Board-certification is, without a doubt, one important measure of professional competence. If any one of us becomes convinced, however, that only physicians who have passed one particular written and oral examination (usually our own) are competent, we are, at that moment, narrow-minded and guilty of chauvinism in its purest form. Training and experience are also essential measures of a physician's qualifications.

The true measure of one's competence lies in the quality of work performed over a period of time. Board-certification alone cannot bestow the same degree of competence to every member of a profession. Even those of us who completed the requisite training and passed the identical exam given by our respective certifying boards possess varying degrees of interest and expertise within our chosen specialty.

As part of a well-conceived marketing campaign, some medical groups have taken isolated bad surgical results of competing physicians to the media. Any physician who claims to never have had an unfavorable result is either not practicing medicine, is oblivious, or is not being truthful. For every unfortunate mishap occurring in the hands of any one group of physicians, numerous examples of catastrophies at the hands of an opposing group could also be produced. Airing "dirty laundry" only denigrates our profession and provokes suspicion on the part of the public. If the facts were revealed, many of those "casting stones" at colleagues could be embarrassed by a public disclosure of their own files.

Shakespeare wrote about the fault-finder, ". . . it is his nature's plague to spy into abuses; and oft his jealousy shapes faults that are not." Jealousy and/or protection of "turf" can cause unprofessional behavior among professionals, is divisive, provides grounds for disciplinary action, and fans the malpractice fires.

So, how does the medical profession guard against self-destruction? First we must always strive to upgrade the quality of care our profession delivers and encourage colleagues to acquire all the training and knowledge within their capabilities. Such an objective is constructive and helps everyone. The course sug-

gested by some health care providers with self-serving advertising campaigns denigrating colleagues is destructive. An honest appraisal of the motives of those claiming to be "serving the public's interest" might reveal a selfish attempt to exclude competition. Regardless of the arena, champions welcome and seek out competition while the weak and insecure hide behind man-made barriers they build for "protection."

Hippocrates advised physicians to teach and share our art with our fellow physicians, as one brother would with another. Many seem to have lost sight of this charge as they seek to establish medical monopolies at the expense of colleagues equally as qualified to perform like services.

The free enterprise system takes care of inferior products or services. The medical profession now has mechanisms to deal with the inept, incompetent, or delinquent. The American public no longer takes things at face value. Today's patients are more inquisitive and demanding. Inferior products or professional services cannot endure in a capitalistic system, at least not for very long.

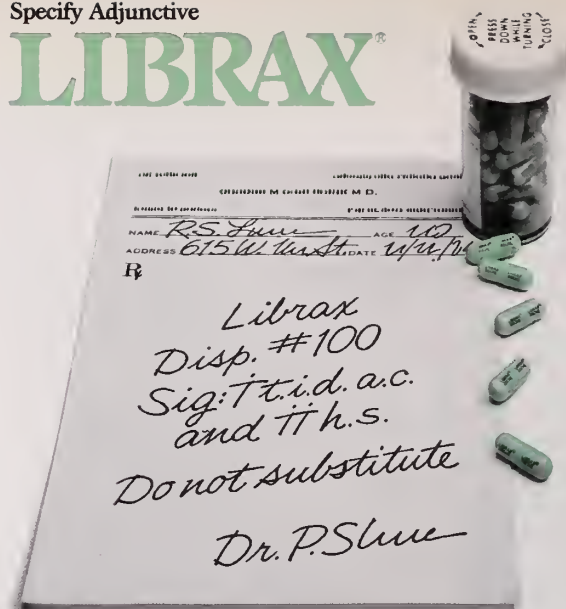
This is the same system which has allowed our country and this profession to be the most envied in the world. Doctors, however, must be careful not to embrace Madison Avenue tactics of those selling disposable products either. The health care industry is free to market its services, but let us also be free of practices which shall be destructive in nature.

In "The Eagle and the Arrow," Aesop describes the final scene in which the mighty eagle, who once soared higher than the rest of the species, lies dead. "... the arrow had been feathered with one of the eagle's own plumes." He continued, "we often give our enemies the means of our own destruction. . . ."

The physician community needs to look within its own ranks for the answers to some of our problems. Although the arrow has been launched, it has not yet hit its mark. In this scenario, the eagle may have a second change. It will take all of us working together to have a chance to save our profession from those who would tear us apart from the inside and then engulf us. □

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- * **Indications:** Based on a review of this drug by the National Academy of Sciences—National Research Council and/or other information, FDA has classified the indications as follows: "Possibly" effective: as adjunctive therapy in the treatment of peptic ulcer and in the treatment of the irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis. Final classification of the less-than-effective indications requires further investigation.

Contraindications: Glaucoma; prostatic hypertrophy, benign bladder neck obstruction; hypersensitivity to chlordiazepoxide HCl and/or clidinium Br.

Warnings: Caution patients about possible combined effects with alcohol and other CNS depressants, and against hazardous occupations requiring complete mental alertness (e.g., operating machinery, driving). Physical and psychological dependence rarely reported on recommended doses, but use caution in administering Librium® (chlordiazepoxide HCl/Roche) to known addiction-prone individuals or those who might increase dosage; withdrawal symptoms (including convulsions) reported following discontinuation of the drug.

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As with all anticholinergics, inhibition of lactation may occur. **Precautions:** In elderly and debilitated, limit dosage to smallest effective amount to preclude ataxia, oversedation, confusion (no more than 2 capsules/day initially; increase gradually as needed and tolerated). Though generally not recommended, if combination therapy with other psychotropics seems indicated, carefully consider pharmacology of agents, particularly potentiating drugs such as MAO inhibitors, phenothiazines. Observe usual precautions in presence of impaired renal or hepatic function. Paradoxical reactions reported in psychiatric patients. Employ usual precautions in treating anxiety states with evidence of impending depression; suicidal tendencies may be present and protective measures necessary. Variable effects on blood coagulation reported very rarely in patients receiving the drug and oral anticoagulants; causal relationship not established.

Adverse Reactions: No side effects or manifestations not seen with either compound alone reported with Librax. When chlordiazepoxide HCl is used alone, drowsiness, ataxia, confusion may occur, especially in elderly and debilitated; avoidable in most cases by proper dosage adjustment, but also occasionally observed at lower dosage ranges. Syncope reported in a few instances. Also encountered: isolated instances of skin eruptions, edema, minor menstrual irregularities, nausea and constipation, extrapyramidal symptoms, increased and decreased libido—all infrequent, generally controlled with dosage reduction; changes in EEG patterns may appear during and after treatment; blood dyscrasias (including agranulocytosis), jaundice, hepatic dysfunction reported occasionally with chlordiazepoxide HCl, making periodic blood counts and liver function tests advisable during protracted therapy. Adverse effects reported with Librax typical of anticholinergic agents, i.e., dryness of mouth, blurring of vision, urinary hesitancy, constipation. Constipation has occurred most often when Librax therapy is combined with other spasmolytics and/or low residue diets.



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*Librax has been evaluated as possibly effective as adjunctive therapy in the treatment of peptic ulcer and the irritable bowel syndrome.

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Cat Scratch Disease

Phillip M. Klein, M.D., F.A.A.P.*

Abstract

A 1987 review of cat scratch disease is presented with the etiologic agent identified. Its diagnosis and clinical signs, the possibility of the AIDS virus now included in the differential diagnosis. Treatment with medical and/or surgical options are discussed.

History

The entity cat scratch disease (CSD) or cat scratch fever was first described by Debre,¹ in France, in the 1930s.

It occurs more frequently in the fall and winter months, predominantly in the colder climates, because survival of the organism in temperatures that are more suitable allows for bacteria replication in and on the animal host.

It has become the organism responsible for the syndrome of Parinaud's² or oculoglandular disease recognized by Parinaud as early as 1889.^{3, 4}

To prove Koch's postulates it took approximately 35 years before a group, under the leadership of Wear,⁵ to isolate a bacillus that most workers in the field believe is the etiologic agent. Margileth,⁶ one of the authorities, has written extensively on the subject and since 1984 has continued to isolate the same gram

negative bacillus from the skin and lymph nodes after the initial insult by the cat at the primary site, and its regional extension, the lymph node.⁷ The organism is apparently a very fastidious one requiring for its nutrition the ambience of an early abscess and possible granulation tissue-like areas.

The ability to stain the bacillus is not a simple one, requiring the Whartin-Starry silver impregnation technique.⁸ The organism also stains weakly Gram negative, although some workers have experienced the cell wall staining Gram positive. The controversy in Gram staining exists because the organism has a very poor cell wall, or none at all, identified in fields of the electron microscope. Constant reproductions of the same organism have been accomplished when the Whartin-Starry stain has been correctly applied, and absolute criteria been meticulously followed. The organisms are not acid fast according to Boyd and Craig.⁹

Previous to the confirmation by Wear, it was thought to be a fungus, a virus or even a mycoplasma like organism. None of these possible isolates were ever confirmed.

There is verification of a bacterial existence by Kitchel¹⁰ and co-workers. The bacillary organism has also been isolated and visualization occurs with the Whartin-Starry stain, the organism is present in the pre-necrotic granular tissue. Gerber,¹¹ in 1985, described the same organism that Wear and Margileth identified: its source was a CSD lymph node.

Growth is positive, in vitro, through extensive techniques both aerobically and anaerobically. Electron mi-

continued on page 21

* Phillip M. Klein, M.D., Parish Clinic, P.O. Box 376, Parrish, Alabama 35580

Before prescribing, see complete prescribing information in SK&F LAB CO. literature or PDR. The following is a brief summary.

Contraindications: There are no known contraindications to the use of 'Tagamet'.

Precautions: While a weak antiandrogenic effect has been demonstrated in animals, 'Tagamet' has been shown to have no effect on spermatogenesis, sperm count, motility, morphology or in vitro fertilizing capacity in humans.

In a 24-month toxicity study in rats at dose levels approximately 9 to 56 times the recommended human dose, benign Leydig cell tumors were seen. These were common in both the treated and control groups, and the incidence became significantly higher only in the aged rats receiving 'Tagamet'.

Rare instances of cardiac arrhythmias and hypotension have been reported following the rapid administration of 'Tagamet' HCl (brand of cimetidine hydrochloride) injection by intravenous bolus.

Symptomatic response to 'Tagamet' therapy does not preclude the presence of a gastric malignancy. There have been rare reports of transient healing of gastric ulcers despite subsequently documented malignancy.

Reversible confusional states have been reported on occasion, predominantly in severely ill patients.

'Tagamet' has been reported to reduce the hepatic metabolism of warfarin-type anticoagulants, phenytoin, propranolol, chlorthalidone, diazepam, lidocaine, theophylline and metronidazole. Clinically significant effects have been reported with the warfarin anticoagulants; therefore, close monitoring of prothrombin time is recommended, and adjustment of the anticoagulant dose may be necessary when 'Tagamet' is administered concomitantly. Interaction with phenytoin, lidocaine and theophylline has also been reported to produce adverse clinical effects.

However, a crossover study in healthy subjects receiving either 'Tagamet' 300 mg. q.i.d. or 800 mg. h.s. concomitantly with a 300 mg. b.i.d. dosage of theophylline (Theo-Dur®, Key Pharmaceuticals, Inc.),

demonstrated less alteration in steady-state theophylline peak serum levels with the 800 mg. h.s. regimen, particularly in subjects aged 54 years and older. Data beyond ten days are not available. (Note: All patients receiving theophylline should be monitored appropriately, regardless of concomitant drug therapy.)

Lack of experience to date precludes recommending 'Tagamet' for use in pregnant patients, women of childbearing potential, nursing mothers or children under 16 unless anticipated benefits outweigh potential risks; generally, nursing should not be undertaken in patients taking the drug since cimetidine is secreted in human milk.

Adverse Reactions: Diarrhea, dizziness, somnolence, headache, rash. Reversible arthralgia, myalgia and exacerbation of joint symptoms in patients with preexisting arthritis have been reported. Reversible confusional states (e.g., mental confusion, agitation, psychosis, depression, anxiety, hallucinations, disorientation), predominantly in severely ill patients, have been reported. Gynecomastia and reversible impotence in patients with pathological hypersecretory disorders receiving 'Tagamet', particularly in high doses, for at least 12 months, have been reported. Reversible alopecia has been reported very rarely. Decreased white blood cell counts in 'Tagamet'-treated patients (approximately 1 per 100,000 patients), including agranulocytosis (approximately 3 per million patients), have been reported, including a few reports of recurrence on rechallenge. Most of these reports were in patients who had serious concomitant illnesses and received drugs and/or treatment known to produce neutropenia. Thrombocytopenia (approximately 3 per million patients) and a few cases of aplastic anemia have also been reported. Increased serum transaminase and creatinine, as well as rare cases of fever, interstitial nephritis, urinary retention, pancreatitis and allergic reactions, including hypersensitivity vasculitis, have been reported. Reversible adverse hepatic effects, cholestatic or mixed cholestatic-hepatocellular in nature, have been reported rarely. Because of the predominance of cholestatic features, severe parenchymal injury is considered highly un-

likely. A single case of biopsy-proven periportal hepatic fibrosis in a patient receiving 'Tagamet' has been reported.

How Supplied: Tablets: 200 mg. tablets in bottles of 100; 300 mg. tablets in bottles of 100 and Single Unit Packages of 100 (intended for institutional use only); 400 mg. tablets in bottles of 60 and Single Unit Packages of 100 (intended for institutional use only), and 800 mg. Tiltab® tablets in bottles of 30 and Single Unit Packages of 100 (intended for institutional use only).

Liquid: 300 mg./5 ml., in 8 fl. oz. (237 ml.) amber glass bottles and in single-dose units (300 mg./5 ml.), in packages of 10 (intended for institutional use only).

Injection:

Vials: 300 mg./2 ml. in single-dose vials, in packages of 10 and 30, and in 8 ml. multiple-dose vials, in packages of 10 and 25.

Prefilled Syringes: 300 mg./2 ml. in single-dose prefilled disposable syringes.

Plastic Containers: 300 mg. in 50 ml. of 0.9% Sodium Chloride in single-dose plastic containers, in packages of 4 units. No preservative has been added.

ADD-Vantage® Vials: 300 mg./2 ml. in single-dose, ADD-Vantage® Vials, in packages of 25.

Exposure of the premixed product to excessive heat should be avoided. It is recommended the product be stored at controlled room temperature. Brief exposure up to 40°C does not adversely affect the premixed product.

'Tagamet' HCl (brand of cimetidine hydrochloride) injection premixed in single-dose plastic containers is manufactured for SK&F Lab Co. by Travenol Laboratories, Inc., Deerfield, IL 60015.

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BRS-TG-L73B

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WARNING

This drug is not indicated for initial therapy of edema or hypertension. Edema or hypertension requires therapy titrated to the individual. If this combination represents the dosage so determined, its use may be more convenient in patient management. Treatment of hypertension and edema is not static, but must be reevaluated as conditions in each patient warrant.

Contraindications: Concomitant use with other potassium-sparing agents such as spironolactone or amiloride. Further use in anuria, progressive renal or hepatic dysfunction, hyperkalemia. Pre-existing elevated serum potassium. Hypersensitivity to either component or other sulfonamide-derived drugs.

Warnings: Do not use potassium supplements, dietary or otherwise, unless hypokalemia develops or dietary intake of potassium is markedly impaired. If supplementary potassium is needed, potassium tablets should not be used. Hyperkalemia can occur, and has been associated with cardiac irregularities. It is more likely in the severely ill, with urine volume less than one liter/day, the elderly and diabetics with suspected or confirmed renal insufficiency. Periodically, serum K⁺ levels should be determined. If hyperkalemia develops, substitute a thiazide alone, restrict K⁺ intake. Associated widened QRS complex or arrhythmia requires prompt additional therapy. Thiazides cross the placental barrier and appear in cord blood. Use in pregnancy requires weighing anticipated benefits against possible hazards, including fetal or neonatal jaundice, thrombocytopenia, other adverse reactions seen in adults. Thiazides appear and triamterene may appear in breast milk. If their use is essential, the patient should stop nursing. Adequate information on use in children is not available. Sensitivity reactions may occur in patients with or

without a history of allergy or bronchial asthma. Possible exacerbation or activation of systemic lupus erythematosus has been reported with thiazide diuretics.

Precautions: The bioavailability of the hydrochlorothiazide component of 'Dyazide' is about 50% of the bioavailability of the single entity. Theoretically, a patient transferred from the single entities of triamterene and hydrochlorothiazide may show an increase in blood pressure or fluid retention. Similarly, it is also possible that the lesser hydrochlorothiazide bioavailability could lead to increased serum potassium levels. However, extensive clinical experience with 'Dyazide' suggests that these conditions have not been commonly observed in clinical practice. Angiotensin-converting enzyme (ACE) inhibitors can elevate serum potassium; use with caution with 'Dyazide'. Do periodic serum electrolyte determinations (particularly important in patients vomiting excessively or receiving parenteral fluids, and during concurrent use with amphotericin B or corticosteroids or corticotropin (ACTH)). Periodic BUN and serum creatinine determinations should be made, especially in the elderly, diabetics or those with suspected or confirmed renal insufficiency. Cumulative effects of the drug may develop in patients with impaired renal function. Thiazides should be used with caution in patients with impaired hepatic function. They can precipitate coma in patients with severe liver disease. Observe regularly for possible blood dyscrasias, liver damage, other idiosyncratic reactions. Blood dyscrasias have been reported in patients receiving triamterene, and leukopenia, thrombocytopenia, agranulocytosis, and aplastic and hemolytic anemia have been reported with thiazides. Thiazides may cause manifestation of latent diabetes mellitus. The effects of oral anticoagulants may be decreased when used concurrently with hydrochlorothiazide; dosage adjustments may be necessary. Clinically insignificant reductions in arterial responsiveness to norepinephrine have been reported. Thiazides have also been shown to increase the paralyzing effect of nondepolarizing muscle relaxants such as tubocurarine. Triamterene is a weak folic acid antagonist. Do periodic blood studies in cirrhotics with splenomegaly. Antihypertensive effects may be enhanced in post-sympathectomy patients. Use cautiously in surgical patients. Triamterene has been found in renal stones in association with the other usual calculus components. Therefore, 'Dyazide' should be used with caution in patients with histories of stone formation. A few occurrences of acute renal failure have been reported in patients on 'Dyazide' when treated with indomethacin. Therefore, caution is advised in administering nonsteroidal anti-inflammatory agents with 'Dyazide'. The

following may occur: transient elevated BUN or creatinine or both, hyperglycemia and glycosuria (diabetic insulin requirements may be altered), hyperuricemia and gout, digitalis intoxication (in hypokalemia), decreasing alkali reserve with possible metabolic acidosis. 'Dyazide' interferes with fluorescent measurement of quinidine. Hypokalemia is uncommon with 'Dyazide', but should it develop, corrective measures should be taken such as potassium supplementation or increased dietary intake of potassium-rich foods. Corrective measures should be instituted cautiously and serum potassium levels determined. Discontinue corrective measures and 'Dyazide' should laboratory values reveal elevated serum potassium. Chloride deficit may occur as well as dilutional hyponatremia. Concurrent use with chlorpropamide may increase the risk of severe hyponatremia. Serum PBI levels may decrease without signs of thyroid disturbance. Calcium excretion is decreased by thiazides. 'Dyazide' should be withdrawn before conducting tests for parathyroid function. Thiazides may add to or potentiate the action of other antihypertensive drugs. Diuretics reduce renal clearance of lithium and increase the risk of lithium toxicity.

Adverse Reactions: Muscle cramps, weakness, dizziness, headache, dry mouth; anaphylaxis, rash, urticaria, photosensitivity, purpura, other dermatological conditions; nausea and vomiting, diarrhea, constipation, other gastrointestinal disturbances; postural hypotension (may be aggravated by alcohol, barbiturates, or narcotics). Necrotizing vasculitis, paresthesias, icterus, pancreatitis, xanthopsia and respiratory distress including pneumonitis and pulmonary edema, transient blurred vision, sialadenitis, and vertigo have occurred with thiazides alone. Triamterene has been found in renal stones in association with other usual calculus components. Rare incidents of acute interstitial nephritis have been reported. Impotence has been reported in a few patients on 'Dyazide', although a causal relationship has not been established.

Supplied: 'Dyazide' is supplied as a red and white capsule, in bottles of 1000 capsules; Single Unit Packages (unit-dose) of 100 (intended for institutional use only); in Patient-Pak™ unit-of-use bottles of 100.

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croscopy further identifies the organism. Studies as far back as 1953 by Cassidy¹² put to rest the theory that a saprophytic "leptothrix" was the etiological agent of CSD.¹³ Others have similarly concluded that by using a variety of biochemical and staining techniques leptothrix is not the offending organism.¹⁴

Gerber¹¹ and his group postulate that reasons for the inadequate growth and recovery of the offending organism rests with the timing of specimen recovery. Their studies indicate that by the time the lymph gland has become visible in size, the disease is in the late phase, and few viable organisms are apparent. The success of the recovery of the fastidious organisms depends upon the culturing in the early phase such as a biopsy of the skin or conjunctival lesion.

Carithers,⁴ has disputed the validity of the bacillus of CSD and concluded that the organism Wear and Margileth have identified may be a fortuitous one, and is probably not the likely culprit. However, the studies of Wear, Margileth and Gerber remain the hallmark until all of Koch's postulates can be satisfied.

The organism and its resultant problems most often present in the age group from five to twenty years and sometimes is diagnosed in the 30 to 40 age group. Family outbreaks have occurred.

Since its transmission is via the scratch of a cat, and rarely from other animals, the history usually reveals a cat contact one to four weeks previous. Most reviews and case histories implicate the younger animals, those less than six months of age, above the older, stable, family pet.

The common clinical adenitis is a result of a scratch or lesion becoming a papule, with or without induration. There may exist an inoculation nodule, and pruritis at the site of entry, persisting sometimes for one or two weeks. The most common form physicians come in contact with is the enlarged lymph node usually distal to the site of entry. Presentation site is the axilla, cervical neck, submandibular and other areas. In many cases this lymphadenopathy develops ten to twenty one days after the primary inoculation from the scratch. The degree of reporting grows with the awareness as the numbers of cases rise yearly. It is by far the most common cause of adenitis in children. Clinicians, rarely, if ever, report bilateral involvement.

Signs and Symptoms

CSD usually presents as a tenderness, swelling and an enlargement of a lymph gland in the area of the neck exciting the parents to come forward and inquire as to its causes. Presentation occurs without fever in half of the cases. Many times the main complaint is a headache or a complication from encephalitis to an

osteolytic lesion being reported. Most uncommon presentations such as convulsions,¹⁵ thrombolytic and nonthrombolytic purpura¹⁶ have been reported, as has hemolytic anemia.¹⁷

However, the regional solitary lymphadenopathy without any other generalized evidences, is the commonest, and should be considered the primary cause of the lump when no other reason is found for the enlargement out of proportion to an entity that is understandable and logical extension of an infection or disease process. I have seen patients with nodes proximal to the inguinal area from unusual cat scratches on the legs or ankles. However, the usual distal site from the hands and arms is the commonest presentation in toddlers and older children.

Many authorities, especially Margileth, agree that at least three to four major criteria must be established to make a definitive diagnosis:

- 1) Animal contact with a skin lesion
- 2) A positive CSD skin test
- 3) Negative laboratory studies for other causes of lymphadenopathy
- 4) The characteristic histopathology, if a biopsy is taken.

Numerous problems arise from the fourth criteria and it is the consensus that more harm is done to biopsy the lesion, than to allow it to resolve spontaneously, as they do within three to four weeks, many without the aid of antibiotics.

Sinus tracts and extended involvement is the usual history when surgery has interrupted the normal benign cycle of the disease. Attempts to use adrenal corticosteroids have not been beneficial.

The treatment usually consists of local heat application and pain relief. If it becomes necessary to remove the node, most agree that needle aspiration is preferable to surgical incision since the regression is usually satisfactory and the resultant disappearance of the node occurs. Laboratory tests are not diagnostic of the disease. It is sometimes necessary, in children and young adults, to test for the presence of the heterophile antibodies as a rule out because of the usual and common site of early nodal involvement of infectious mononucleosis in the neck area.

In making a diagnosis, the criteria of a positive skin test is sometimes fraught with problems. Firstly, the skin test antigen has been implicated to contain the organism.¹⁸ However, Margileth recently has prepared antigen that has eliminated this problem.¹⁹

The skin test antigen, if used correctly, is very specific. The response is a delayed hypersensitivity type reaction. Much discussion is present in the literature regarding the making of the antigen. Some workers feel that the disease can be spread if the antigen is not properly prepared. Since no commercially prepared antigen is presently available, its use has become lim-

ited. Sometimes conversion possibility can be delayed for up to four weeks. Margileth states that the cutaneous reactivity of the scratch antigen can last up to ten years. Some clinicians advocate a skin punch biopsy if doubt exists as to the diagnosis. However, node biopsy, as noted, is not the primary treatment due to the complications that may result, namely, fistulas.

Marcey,²⁰ has extensively reviewed the causes of adenitis of the neck and concluded that most common organisms, if present, manifest within four to seven days of onset of infection. The adenitis of CSD is one of gradual onset and without high fever and pain as opposed to the infections due to staphylococcus aureus or beta hemolytic streptococci. Adenopathy from these usually present with high fever, tenderness, and commonly erythema. The unilateral occurrence of an infective node is obvious. In the opposite case a solitary silent appearing CSD nodule or swelling with its insidious nature and development is more provocative.

Extensions of the Complication

Convulsions,²¹ Jacksonian-like seizures,²² muscle weakness,²³ paresis,²³ Bell's palsy,²³ choreiform movements,²⁴ coma,²⁴ vasculitis with cerebral arteritis,²⁴ transverse myelitis,²⁵ encephalitis,^{15, 26} osteolytic lesions,²⁷ pneumonia,²⁸ generalized dermatitis,²⁹ and optic neuritis³⁰ have been associated with CSD as complications, much worse than the common node involvement.

Differential Diagnosis

The differential diagnosis must include tuberculosis, beta hemolytic streptococci, staphylococci, brucella, infectious mononucleosis, histoplasmosis, osteomyelitis, tularemia, syphilis, and lastly tumors, both benign and malignant.

Eye involvement, historically, has been present in 5 to 10% of the patients.¹² This demonstrates as a hyperemia and/or preauricular swelling with possible exudation. Cultures are usually negative. The original syndrome of Parinaud² is now believed to be a variation of the disease.

In view of the present-day AIDS epidemic and the prevalence of the AIDS-related virus (ARV) in both the pediatric and young adult population, depending upon the age and history of the patient this is another serious consideration that must be entertained, since there is a close clinical attachment of the TB organism and the AIDS virus, one must entertain this possibility if obvious CSD is not presented quickly in the diagnostic and clinical study. Search of the literature has not revealed this combination of events.

Treatment and Diagnosis

The prognosis is excellent. The treatment is outlined previously, may necessitate the use of antibiotics if there is any suspicion that bacterial contamination at

the entrance site other than the cat scratch organism itself may be present to complicate the course of the disease.

The best therapy, of course, is reassurance that the enlargement will regress within two to three weeks unless suppuration occurs. Berkow³¹ states that tetracycline may shorten the course of the disease. Antibiotic sensitivity of cultures of the isolated organisms of Gerber¹¹ revealed a sensitivity to penicillin, erythromycin, cephalothin and clindamycin. Regression of the adenopathy usually occurs in several weeks or a maximum of two to three months with attention to the relief of pain with analgesics and if fluctuant mass develops, aspiration. This is by needle aspiration as noted previously.

Until recently, it was thought that complete recovery ensued and immunity was lifelong. However, Margileth³² has reported a study of 23 patients with a prolonged course of their disease. Besides the normal benign signs and symptoms, several of these patients suffered serious complications, such as neuroretinitis, arthritis, pleurisy, and splenomegaly, together with the CSD nodal involvement reoccurring during separate episodes. Since no other cause for these events could be found, other than the presence of the CSD bacilli in the nodes, and ultimately, complete recovery occurred, it was presumed they were genuine CSD infections.

The lack of response to any form of antibiotic therapy is recorded from thousands of patients followed, both in the literature, and in clinical practice.³³ Greenbaum¹⁷ studied a case of CSD with inguinal nodes and hepatosplenomegaly extensively and her studies were entirely negative for bacteria and fungi. They did visualize gram negative pleomorphic organisms with the Whartin-Starry stain. The patient had hemolytic anemia. The nodes disappeared within two months and the patient had a complete recovery.

The literature abounds with cases that resolve spontaneously, in spite of aggressive therapy, surgical, medical, or purposeful neglect. □

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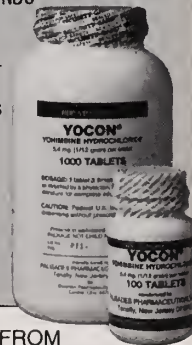
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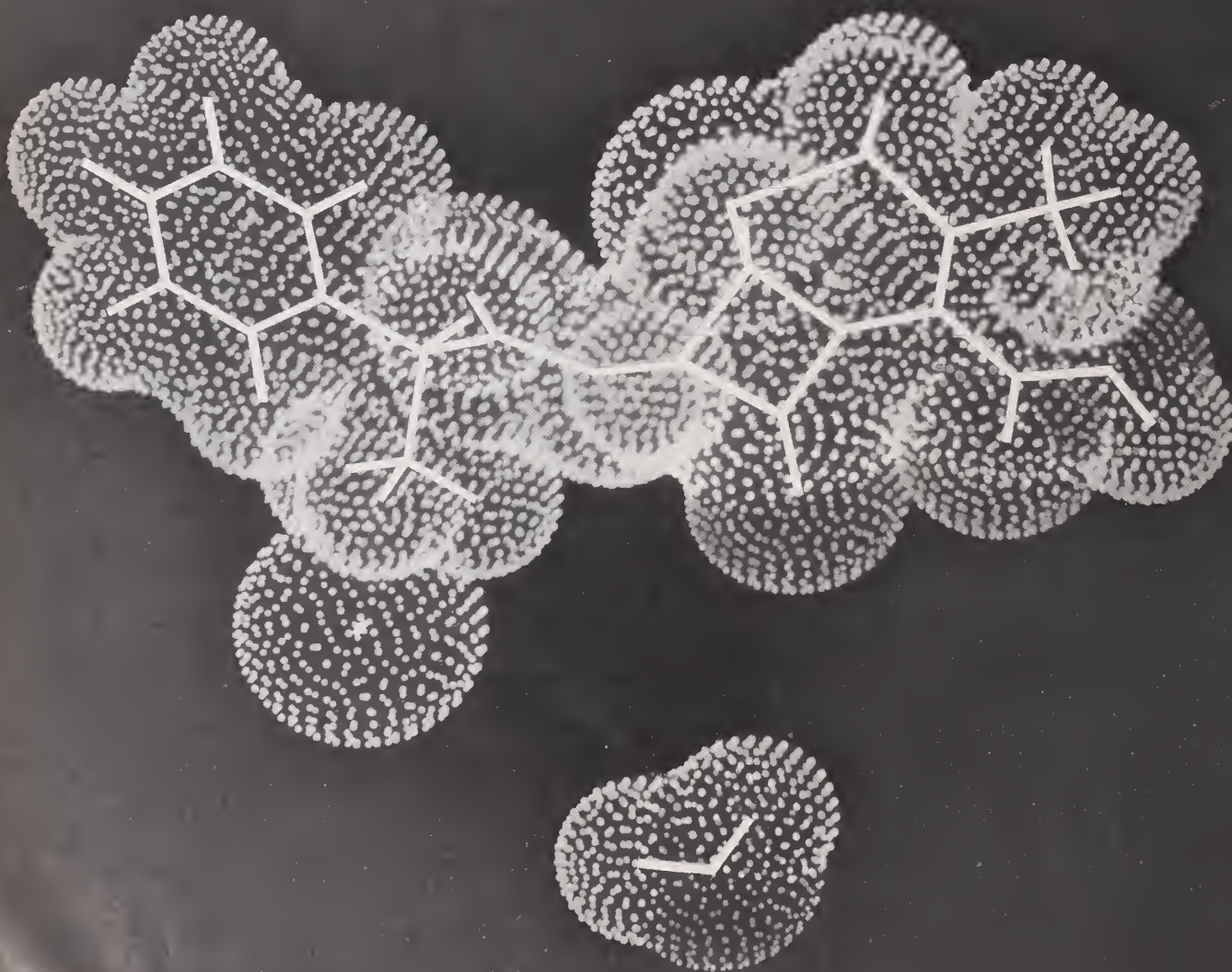
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Enterococcal Endocarditis: Recent Experience

LeRoy F. Harris, M.D.*

Abstract

We compared seven cases of enterococcal endocarditis from the hospitals of a single community to previous series all of which originated from university or tertiary care hospitals. In agreement with earlier series we found enterococci to rank behind viridans streptococci and staphylococci as the third leading cause of endocarditis and enterococcal endocarditis to present in a subacute fashion with fever and heart murmur. Unlike previous series none of our patients were women of child-bearing age and rarely our patients possessed antecedent cardiac valvular disease or a predisposing genitourinary condition. The treatment of enterococcal endocarditis is complicated by the lack of bactericidal activity of single antibiotics and by the increasing resistance of enterococci to antimicrobial agents. Recommended therapy consists of parenteral penicillin or ampicillin combined with streptomycin or gentamicin in cases of streptomycin-resistant enterococci. The mortality rate in our series was 14 percent and none of our patients has relapsed.

Enterococci are well recognized etiologic agents for a number of infections including bacteremia, urinary tract infection and meningitis.¹ Recently enterococci have emerged as superinfections in patients receiving third generation cephalosporin antibiotics² and in immunocompromised hosts.³ Traditionally enterococci account for 10 to 20 percent of cases of endocarditis but most series of enterococcal endocarditis are reported from university or tertiary care hospitals⁴⁻⁷ and their comparability to community hospitals is unknown. We present our experience with enterococcal endocarditis from the hospitals of a single community and compare our cases with previous series.

Patients and Methods

We reviewed the charts of all patients with a final discharge diagnosis of infectious endocarditis admitted to the three community hospitals of Huntsville, Alabama, during the nine-year period of 1978 through 1987, inclusive. Endocarditis was defined as a compatible clinical illness if two or more blood cultures contained the same organism. Although not required for inclusion in this series, surgical or autopsy confirmation of the diagnosis was sought whenever possible. Endocarditis was considered to be caused by enterococci when blood cultures contained only those organisms. Charts of all patients with enterococcal endocarditis were examined in greater detail. Enterococci were identified on Gram stain as gram-positive cocci; they yielded a negative catalase reaction and grew in bile-esculin medium and trypticase soy broth

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* LeRoy F. Harris, M.D., Clinical Associate Professor of Medicine, School of Primary Medical Care, University of Alabama in Huntsville, 410 Lowell, Huntsville, Alabama 35801.

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Enterococcal Endocarditis

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with 6.5% sodium chloride. Serum cidal levels were performed by the modified Schlichter serum antibacterial potency test. A metastatic infection was defined as an infection which arose hematogenously from an infected heart valve.

Results

Table 1 lists the number and percentage due to individual organisms of 50 cases of endocarditis. Viridans streptococci accounted for 15 cases (30%) followed by coagulase-negative staphylococci 10 cases (20%), *Staphylococcus aureus* 9 cases (18%), enterococci 7 cases (14%), nonenterococcal group D streptococci 4 cases (8%) and other bacteria 5 cases (10%).

Table 1

Infectious Endocarditis — Huntsville, Alabama, 1978-1987

Organism	Number of Cases	(%)
Viridans streptococci	15	(30)
Coagulase-negative staphylococci	10	(20)
<i>Staphylococcus aureus</i>	9	(18)
Enterococci	7	(14)
Nonenterococcal group D streptococci	4	(8)
Other	5	(10)
Total	50	(100)

Note: Other = group B streptococci 2 (4), group G streptococci 1 (2), *Cardiobacterium hominis* 1 (2), *Neisseria subflava* 1 (2).

Table 2 describes the clinical features of seven patients with enterococcal endocarditis. The patients ranged in age from 47 to 81 years and averaged 58 years. All but one patient were males. Underlying diseases were present in five patients and included hypertension, aortic stenosis, recurrent urinary tract infection, chronic renal failure maintained on continuous ambulatory peritoneal dialysis and lymphoma. The aortic valve was infected in five cases and the mitral valve in three cases including one patient with coexisting aortic and mitral valve involvement. The commonest symptom of the patients was fever and less frequently musculoskeletal pain, weight loss and dyspnea. Cardiac murmurs were appreciated in all but one patient and a Janeway lesion was present in one patient. The maximum temperature during the first 24 hours of hospitalization extended from 98.4 to 100.4°F and averaged 99.4°F.

Table 3 delineates the laboratory, radiographic and echocardiographic findings of seven cases of enterococcal endocarditis. The leukocyte count on admission to the hospital ranged from 4000 to 27500 per cu mm and averaged 12660 per cu mm. The serum bactericidal level drawn within two hours of administration of both antibiotics (peak serum cidal level) was obtained on five patients and extended from 1:4 to 1:256. The chest x-ray on admission to the hospital was normal in five patients and revealed pulmonary edema and cardiomegaly in the other two patients, respectively. Echocardiography was performed on four patients and disclosed no vegetations in two patients, a calcified aortic valve in one patient and an aortic vegetation in one patient.

Table 2

Enterococcal Endocarditis — Clinical Features

Case	Age/Sex	Underlying Disease	Valve Involved	Symptoms	Signs	T max (°F)
1	58/M	Hypertension	Mitral	Fever — 4 mo	Sys M, Janeway lesion	100.4
2	81/F	Aortic stenosis	Aortic	Fever, weight loss, dyspnea — 2 mo	Sys M	99
3	47/M	None	Aortic	Fever, weight loss, dyspnea — 3 mo	Sys and dias M	99.2
4	50/M	Recurrent UTI	Mitral	Low back and hip pain — 1 mo	None	100.2
5	50/M	CRF with CAPD	Mitral and aortic	Bilateral arm pain — 1 mo	Sys M	98.4
6	65/M	None	Aortic	Fever — 10 d	Sys M	99.4
7	55/M	Lymphoma	Aortic	Fever — 3 wk	Sys and dias M	99.2

Note: T max = maximum temperature during first 24 h of hospitalization, sys = systolic, M = Murmur, dias = diastolic, UTI = urinary tract infection, CRF = chronic renal failure, CAPD = continuous ambulatory peritoneal dialysis.

Table 4 elucidates the treatment, outcome and metastatic infections of seven patients with enterococcal endocarditis. All patients received combination antibiotic therapy with ampicillin and gentamicin in four cases, penicillin and gentamicin in one case, penicillin and streptomycin in one case and vancomycin and gentamicin in one case. Three patients required valve replacement during antimicrobial therapy and valve replacement was performed in one patient three months after completion of antibiotic treatment. In each case congestive heart failure despite medical therapy was the surgical indication. Only one patient died during hospitalization for a 14 percent mortality rate. Two patients suffered metastatic infections in the spine.

Discussion

The group D streptococci are divided into enterococcal and nonenterococcal species by biochemical and physiological tests. Enterococci produce alpha, beta or gamma hemolysis on blood agar and are capable of growing in media containing 40% bile or 6.5% sodium chloride.⁴ The most common enterococcal species are *S. faecalis* and *S. faecium* which account for 80-85% and 15-20% of clinical isolates, respectively. *S. durans* is the least commonly encountered enterococcal species among clinical specimens. It is important to differentiate enterococcal from nonenterococcal species because of the source and pathogenesis of the infections they produce and because of their antimicrobial susceptibility. Enterococci comprise part of the normal gastrointestinal flora and less frequently reside in the oropharynx and vagina.¹

Enterococci rank behind viridans streptococci and staphylococci as the third leading cause of endocarditis and account for 10 to 20 percent of cases.⁸ Enterococci also were our third commonest etiologic agent and were responsible for 14 percent of cases.

Enterococcal endocarditis most frequently occurs in women of childbearing age and in older men with males outnumbering females 2 to 1. This disparity in age reflects the presumed major portal of entry of enterococci, the genitourinary tract. Young women are predisposed to develop enterococcal endocarditis during childbirth, abortion, dilatation and curettage and urethral catheterization and by use of the intrauterine contraceptive device. In older men enterococcal urinary tract infection caused by prostatic hypertrophy can result in enterococcal endocarditis during manipulation of the urinary tract.⁸ Less frequent portals of entry for enterococcal endocarditis include the biliary tract, wounds, oral cavity⁷ and presumably intravenous injection in heroin addicts.⁶ Most patients with enterococcal endocarditis possess antecedent cardiac valvular disease but the infection can involve previously normal valves. The clinical presentation is that of a subacute endocarditis with fever the commonest symptom and heart murmur the most frequent sign. Less often splenomegaly, Roth spots and evidence of peripheral emboli are detected. The mitral valve is involved more commonly than the aortic valve and infrequently patients can exhibit an acute illness with rapid valve destruction.⁸ In our series the patients were predominately elderly and all but one were male. Only one patient each had underlying valvular disease and a predisposing genitourinary condition, respectively. In general our patients demonstrated a subacute course with fever and heart murmur clinically. Of interest were two patients with musculoskeletal complaints due to metastatic infections in the spine. We encountered aortic valve infection more often than mitral valve involvement.

Laboratory data of patients with enterococcal endocarditis reveal a frequent anemia and usually a normal to slightly elevated leukocyte count.⁴ In our ex-

Table 3
Enterococcal endocarditis — Laboratory, Radiographic and Echocardiographic Findings

Case	WBC (Cells/cu mm)	Peak serum cidal level	Chest X-ray	Echocardiogram
1	8800	1:128	Normal	No vegetation
2	12500	1:16	Normal	Calcified aortic valve
3	19400	—	Pulmonary Edema	—
4	6900	1:4	Normal	—
5	27500	—	Cardiomegaly	—
6	9500	1:8	Normal	Aortic vegetation
7	4000	1:256	Normal	No vegetation

Note: WBC = Leukocyte count on admission to hospital, peak serum cidal level = serum bactericidal level drawn within two hours of administration of both antibiotics.

Table 4
Enterococcal Endocarditis — Treatment, Outcome and Metastatic Infection

Case	Treatment		Outcome	Metastatic Infection
	Medical	Surgical		
1	Amp and gent	—	Cure	—
2	Amp and gent	AVR	Cure	—
3	Amp and gent	AVR	Cure	—
4	Pen and gent	—	Cure	Spine
5	Vanco and gent	AVR and MVR	Cure	Spine
6	Pen strep	AVR 3 mo later	Cure	—
7	Amp and gent	—	Death	—

Note: Amp = ampicillin, gent = gentamicin, AVR = aortic valve replacement, pen = penicillin, vanco = vancomycin, MVR = mitral valve replacement.

perience the chest x-ray infrequently was abnormal and the echocardiogram demonstrated a vegetation in only one of the four patients on whom it was performed.

The treatment of enterococcal endocarditis is complicated by the lack of bactericidal activity of single antibiotics and by the increasing resistance of enterococci to antimicrobial agents. The majority of clinical isolates are resistant to the tetracyclines, erythromycin, the penicillinase-resistant penicillins (for example, oxacillin and nafcillin), the cephalosporins and the aminoglycosides. The most active single agents against enterococci include amoxicillin, ampicillin, penicillin G and vancomycin. However, even these antibiotics demonstrate only bacteriostatic as opposed to bactericidal activity which probably accounts for their high rate of failure and relapse when used as single drug therapy for enterococcal endocarditis. Because penicillin in the presence of an aminoglycoside produces synergistic killing of enterococci, combination therapy with both of these agents forms the cornerstone of treatment of enterococcal endocarditis.^{7, 9}

In recent years enterococci have demonstrated increasing resistance to aminoglycosides and thus to synergistic killing of the organisms by combination penicillin-aminoglycoside therapy. All strains of *S. faecium* are resistant to enhanced cidal activity when penicillin is combined with tobramycin or kanamycin. High-level resistance [minimal inhibitory concentration (MIC) greater than or equal to 2000 µg per ml] to streptomycin, occurring in up to 54 percent of clinical isolates of enterococci at one medical center, results in deficient synergistic killing of the organisms by combined penicillin-streptomycin treatment.⁹ A current study has disclosed high-level resistance to gentamicin in over 50 percent of clinical isolates of enterococci at another medical institution,¹⁰ however, such strains have not been documented to cause endocarditis.⁹

In view of the above considerations the following recommendations are made. Patients with streptomycin-susceptible (MIC less than 2000 µg per ml) enterococcal endocarditis should receive penicillin, 20 to 40 million U, or ampicillin, 12 g IV daily, plus streptomycin, 7.5 mg per kg (dose not to exceed 500 mg) IM every 12 hours. Gentamicin, 1 mg per kg (dose not to exceed 100 mg) IM or IV every 8 hours, should be substituted for streptomycin in patients with streptomycin-resistant (MIC greater than or equal to 2000 µg per ml) enterococcal endocarditis. The duration of therapy is four weeks in patients with symptoms of illness present for less than three months and at least six weeks in patients with symptoms present for more than three months and in patients with prosthetic valve endocarditis. Patients who are allergic to penicillin should be desensitized to the agent or if this is not feasible should be treated with vancomycin, 7.5 mg per kg (dose not to exceed 500 mg) IV every 6 hours or 15 mg per kg (dose not to exceed 1 g) IV every 12 hours. The therapy of relapses of enterococcal endocarditis should be modified in the following manner; substitution of gentamicin for streptomycin in streptomycin-resistant isolates, increase in the daily dosage of penicillin or ampicillin to 40 to 100 million U and 12 to 24 g, respectively, and prolongation of treatment to 6 to 8 weeks. The dosage of the aminoglycoside and vancomycin should be reduced in patients with abnormal renal function. Antimicrobial therapy should result in a serum bactericidal level of 1:8 or greater.^{8, 11} In our series a penicillin or vancomycin combined with an aminoglycoside was administered to all patients and achieved a serum bactericidal level of 1:8 or greater in four of the five patients on whom the test was performed. In addition, four of our seven patients eventually required valve replacement because of hemodynamic indications.

continued on page 32

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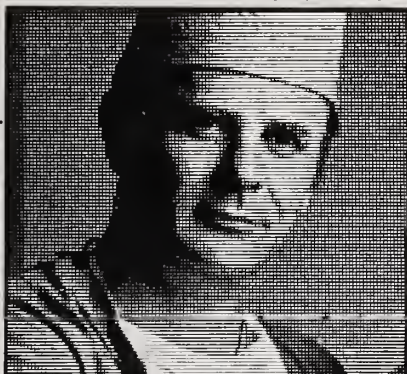
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Enterococcal Endocarditis

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The mortality rate of enterococcal endocarditis has varied from 9 to 47 percent and between 0 to 17 percent of patients have been reported to relapse after treatment.^{4, 5, 7} The mortality rate in our series was 14 percent and none of our patients has relapsed. □

Acknowledgment

The author thanks Juanita Spicer for preparation of the manuscript.

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Opsoclonus and Ataxia Accompanying Acute Gastroenteritis

Jose A. Canedo, M.D.*
Saunders L. Hupp, M.D.*
Williams J. Hamilton, D.O.*

Abstract

Opsoclonus and truncal ataxia developed as concomitants of an acute gastrointestinal illness in a previously healthy young woman. The only neuro-radiologic or laboratory abnormality was a lymphocytic pleocytosis of the cerebral spinal fluid. The patient was begun on a short course of oral steroids with resolution of neurological signs in two weeks.

Introduction

Opsoclonus is a neuro-ophthalmologic disorder characterized by involuntary, rapid, disruptive, multi-directional conjugate saccadic eye movements. These oscillations are usually horizontal, but may have

vertical and rotary components. Additionally, cerebellar dysfunction with myoclonus may occur. Opsoclonus with ataxia has been associated with many diverse conditions including infectious or inflammatory encephalitis, toxins, neoplasia and hydrocephalus.

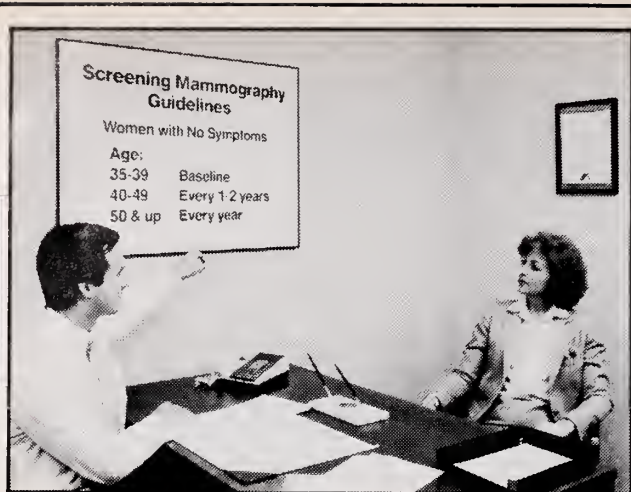
Rarely, an acute, self-limited form of this syndrome has followed a viral respiratory or gastrointestinal illness.¹ We report a case of opsoclonus accompanied by body tremulousness occurring in a healthy young woman following a typical attack of presumed viral gastroenteritis.

Case Report

A 20-year-old, right-handed female experienced nausea, vomiting, diarrhea, chills and neck stiffness associated with a low grade undulating fever. The patient saw her family physician who diagnosed a gastroenteritis and began treatment with oral antibiotics and increased fluids. Several days later, the patient developed incapacitating violent tremors of the entire body, prominent when sitting and standing, but absent while in a recumbent position. Subsequently, the patient was hospitalized at another institution. The following day, she developed oscillopsia in association

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* From the Departments of Neurology (Drs. Canedo, Hamilton) and Surgery, Division of Ophthalmology (Dr. Hupp), University of South Alabama College of Medicine, Mobile, Alabama. Reprint requests: Saunders L. Hupp, M.D., University of South Alabama College of Medicine, P.O. Box 81327, Mobile, Alabama 36689.



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BRIEF SUMMARY

CONTRAINDICATIONS

There are no known contraindications to the use of sucralfate.

PRECAUTIONS

Duodenal ulcer is a chronic, recurrent disease. While short-term treatment with sucralfate can result in complete healing of the ulcer, a successful course of treatment with sucralfate should not be expected to alter the post-healing frequency or severity of duodenal ulceration.

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Carcinogenesis, Mutagenesis, Impairment of Fertility: No evidence of drug-related tumorigenicity was found in chronic oral toxicity studies of 24 months' duration conducted in mice and rats at doses up to 1 gm/kg (12 times the human dose). A reproduction study in rats at doses up to 38 times the human dose did not reveal any indication of fertility impairment. Mutagenicity studies have not been conducted.

Pregnancy: Pregnancy Category B. Teratogenicity studies have been performed in mice, rats, and rabbits at doses up to 50 times the human dose and have revealed no evidence of harm to the fetus due to sucralfate. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when sucralfate is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Adverse reactions to sucralfate in clinical trials were minor and only rarely led to discontinuation of the drug. In studies involving over 2,500 patients, adverse effects were reported in 121 (4.7%). Constipation was the most frequent complaint (2.2%). Other adverse effects, reported in no more than one of every 350 patients, were diarrhea, nausea, gastric discomfort, indigestion, dry mouth, rash, pruritus, back pain, dizziness, sleepiness, and vertigo.

DOSAGE AND ADMINISTRATION

The recommended adult oral dosage for duodenal ulcer is 1 gm four times a day on an empty stomach.

Antacids may be prescribed as needed for relief of pain but should not be taken within one-half hour before or after sucralfate.

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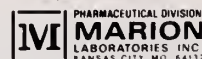
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Opsoclonus and Ataxia

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with the generalized tremors, which led to the patient's transfer to our hospital facility.

Upon admission, the patient appeared ill, unable to sit or stand unassisted and was afebrile. A neuro-ophthalmologic examination revealed vision of 20/200 in the right eye and 20/100 in the left eye. Visual fields to gross confrontation and pupillary reactions were normal. Ocular motility was markedly abnormal with bursts of irregular, chaotic, multi-vectorial, conjugate eye movements which were exacerbated by changes on attempted fixation. These rapid conjugate bursts of eye movements occurred during the initial phase of ocular movement rather than terminally. The anterior and posterior segments of both eyes were normal. In addition to the ocular disturbance, there were continuous abnormal smooth asymmetrical polymyoclonic involuntary movements of the facial muscles associated with head titubation. The remainder of the cranial nerve examination was normal. Also, the patient had significant truncal and to a lesser degree appendicular dystaxia with polymyoclonic jerks occurring only when sitting or standing. The patient was unable to ambulate without two assistants.

The sensory, reflex, structural and vascular examinations were normal. There was no nuchal rigidity and the plantar reflexes were flexor. There was no speech involvement.

The initial laboratory data revealed a normal complete blood cell count, calcium, magnesium, phosphate, liver enzymes and electrolyte levels. The sedimentation rate was 4. The initial lumbar puncture had a normal opening pressure, RBC 400/uncrenated, WBC 125/all lymphocytes, glucose 60 mg/dL, protein 43 mg/dL, VDRL nonreactive with negative gram stain and cultures. A MRI head scan, CT head scan and chest x-ray were normal. The EEG had normal background cortical electrical activity interrupted by artifacts from rapid burst of eye movements lasting three seconds.

A diagnosis of benign focal encephalitis associated with opsoclonus and truncal ataxia was made. The diagnosis was based upon the antecedent viral-type illness coupled with the lymphocytic pleocytosis of the cerebrospinal fluid and normal laboratory and radiologic examinations. The patient was treated with high dose oral steroids tapered over a 10-day period. By the fifth day of steroid treatment, the patient showed significant clinical improvement. She was able to tolerate opening her eyes because of reduced frequency and amplitude of the opsoclonus. There was milder truncal and no appendicular dystaxia. A repeat lumbar puncture was traumatic, with RBC 4350/90% crenated, WBC 13/all lymphocytes, glucose 74 mg/dL,

protein 32 mg/dL, LDH 12 U/L with negative gram stain and cultures. Subsequently, the opsoclonus regressed through stages of ocular flutter and then ocular dysmetria. Two weeks following discharge, the patient was asymptomatic with visual acuity of 20/20 in both eyes and no opsoclonus or truncal ataxia.

Discussion

A multivectorial, chaotic eye movement disorder was first described in 1927 by Orzechowski in association with encephalitis.² Subsequently, opsoclonus has been described in association with Coxsackie B3 infection,³ hemophilus influenza meningitis,⁴ encephalitis,^{1, 5-10} lymphocytic chorio meningitis virus infection,^{1, 5, 7, 11} hydrocephalus,^{1, 3} multiple sclerosis,^{3, 5, 11, 12} DDT intoxication,³ hearing loss,¹³ bronchogenic carcinoma,^{9, 14} breast cancer,^{9, 14} encephalitis with a hypodense cerebellar lesion,⁸ neuroblastoma,^{5, 6, 14, 15} abnormalities of IgG immunoglobulins, and cerebrospinal fluid plasmacytosis.¹⁶

Cogan¹ and Baringer et al⁶ have reported the largest series of opsoclonus in association with upper respiratory or gastrointestinal infections. The course of the illness was self-limited, lasting from 2 weeks to 2 years. These authors suggest only supportive treatment for opsoclonus but some cases have been treated with ACTH or prednisone. No adequate control studies have been done, but retrospective reports suggest a definite clinical improvement on steroid therapy.^{5, 6, 14, 16}

The neuro-anatomic etiology for opsoclonus remains uncertain. In our patient, the regression of opsoclonus through phases of ocular flutter and dysmetria suggest that cerebellar dysfunction had occurred. Savino and Claser reported the same pattern of regression in a patient with neuroblastoma.¹⁷ Other reports infer that the clinical manifestations are due to disturbance in any of several neural pathways regulating motor control. Postulated areas of malfunction include the dentato-rubro-olivary pathways,^{1, 15, 16} the dento-thalamic-cortical connections,^{1, 6, 14-16} or the dentate nuclei.^{1, 3, 14, 16} Neural dysfunction may be mediated by structural, toxic or immunological mechanisms.^{3, 11, 14, 16}

Conclusion

We wish to emphasize the importance of recognizing the benign self-limited nature of the opsoclonus and truncal ataxia syndrome that may rarely accompany an upper respiratory or gastrointestinal illness. A short course of steroids may abbreviate the untoward ocular and truncal symptoms. □

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WARNINGS: FATALITIES ASSOCIATED WITH THE ADMINISTRATION OF SULFONAMIDES, ALTHOUGH RARE, HAVE OCCURRED DUE TO SEVERE REACTIONS, INCLUDING STEVENS-JOHNSON SYNDROME, TOXIC EPIDERMAL NECROLYSIS, FULMINANT HEPATIC NECROSIS, AGRANULOCYTOSIS, APLASTIC ANEMIA AND OTHER BLOOD DYSCRASIAS.

BACTRIM SHOULD BE DISCONTINUED AT THE FIRST APPEARANCE OF SKIN RASH OR ANY SIGN OF ADVERSE REACTION. Clinical signs, such as rash, sore throat, fever, pallor, purpura or jaundice, may be early indications of serious reactions. In rare instances a skin rash may be followed by more severe reactions, such as Stevens-Johnson syndrome, toxic epidermal necrolysis, hepatic necrosis or serious blood disorder. Perform complete blood counts frequently.

BACTRIM SHOULD NOT BE USED IN THE TREATMENT OF STREPTOCOCCAL PHARYNGITIS. Clinical studies show that patients with group A β -hemolytic streptococcal tonsillopharyngitis have a greater incidence of bacteriologic failure when treated with Bactrim than with penicillin.

PRECAUTIONS: General. Give with caution to patients with impaired renal or hepatic function, possible folate deficiency (e.g., elderly, chronic alcoholics, patients on anticonvulsants, with malabsorption syndrome, or in malnutrition states) and severe allergies or bronchial asthma. In glucose-6-phosphate dehydrogenase deficient individuals, hemolysis may occur, frequently dose-related.

Use in the Elderly. May be increased risk of severe adverse reactions in elderly, particularly with complicating conditions, e.g., impaired kidney and/or liver function, concomitant use of other drugs. Severe skin reactions, generalized bone marrow suppression (see WARNINGS and ADVERSE REACTIONS) or a specific decrease in platelets (with or without purpura) are most frequently reported severe adverse reactions in elderly. In those concurrently receiving certain diuretics, primarily thiazides, increased incidence of thrombocytopenia with purpura reported. Make appropriate dosage adjustments for patients with impaired kidney function (see DOSAGE AND ADMINISTRATION).

Use in the Treatment of Pneumocystis Carinii Pneumonitis in Patients with Acquired Immunodeficiency Syndrome (AIDS). Because of unique immune dysfunction, AIDS patients may not tolerate or respond to Bactrim in same manner as non-AIDS patients. Incidence of side effects, particularly rash, fever, leukopenia, with Bactrim in AIDS patients treated for *Pneumocystis carinii* pneumonitis reported to be greatly increased compared with incidence normally associated with Bactrim in non-AIDS patients.

Information for Patients. Instruct patients to maintain adequate fluid intake to prevent crystalluria and stone formation.

Laboratory Tests. Perform complete blood counts frequently, if a significant reduction in the count of any formed blood element is noted, discontinue Bactrim. Perform urinalyses with careful microscopic examination and renal function tests during therapy, particularly for patients with impaired renal function.

Drug Interactions. In elderly patients concurrently receiving certain diuretics, primarily thiazides, an increased incidence of thrombocytopenia with purpura has been reported. Bactrim may prolong the prothrombin time in patients who are receiving the anticoagulant warfarin. Keep this in mind when Bactrim is given to patients already on anticoagulant therapy and reassess coagulation time. Bactrim may inhibit the hepatic metabolism of phenytoin. Given at a common clinical dosage, it increased the phenytoin half-life by 39% and decreased the phenytoin metabolic clearance rate by 27%. When giving these drugs concurrently, be alert for possible excessive phenytoin effect. Sulfonamides can displace methotrexate from plasma protein binding sites, thus increasing free methotrexate concentrations.

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Carcinogenesis, Mutagenesis, Impairment of Fertility. *Carcinogenesis:* Long-term studies in animals to evaluate carcinogenic potential not conducted with Bactrim. *Mutagenesis:* Bacterial mutagenesis studies not performed with sulfamethoxazole and trimethoprim in combination. Trimethoprim demonstrated to be nonmutagenic in the Ames assay. No chromosomal damage observed in human leukocytes *in vitro* with sulfamethoxazole and trimethoprim alone or in combination, concentrations used exceeded blood levels of these compounds following therapy with Bactrim. Observations of leukocytes obtained from patients treated with Bactrim revealed no chromosomal abnormalities. *Impairment of Fertility:* No adverse effects on fertility or general reproductive performance observed in rats given oral dosages as high as 70 mg/kg/day trimethoprim plus 350 mg/kg/day sulfamethoxazole.

Pregnancy. Teratogenic Effects. Pregnancy Category C. Trimethoprim and sulfamethoxazole may interfere with folate acid metabolism; use during pregnancy only if potential benefit justifies potential risk to fetus. Nonteratogenic Effects: See CONTRAINDICATIONS section.

Nursing Mothers: See CONTRAINDICATIONS section.

Pediatric Use: Not recommended for infants under two months (see INDICATIONS and CONTRAINDICATIONS sections).

ADVERSE REACTIONS: Most common are gastrointestinal disturbances (nausea, vomiting, anorexia) and allergic skin reactions (such as rash and urticaria). **FATALITIES ASSOCIATED WITH THE ADMINISTRATION OF SULFONAMIDES, ALTHOUGH RARE, HAVE OCCURRED DUE TO SEVERE REACTIONS, INCLUDING STEVENS-JOHNSON SYNDROME, TOXIC EPIDERMAL NECROLYSIS, FULMINANT HEPATIC NECROSIS, AGRANULOCYTOSIS, APLASTIC ANEMIA AND OTHER BLOOD DYSCRASIAS (SEE WARNINGS SECTION).**

Hematologic: Agranulocytosis, aplastic anemia, thrombocytopenia, leukopenia, neutropenia, hemolytic anemia, megaloblastic anemia, hypoprothrombinemia, methemoglobinemia, eosinophilia. **Allergic Reactions:** Stevens-Johnson syndrome, toxic epidermal necrolysis, anaphylaxis, allergic myocarditis, erythema multiforme, exfoliative dermatitis, angioedema, drug fever, chills, Henoch-Schoenlein purpura, serum sickness-like syndrome, generalized allergic reactions, generalized skin eruptions, photosensitivity, conjunctival and scleral injection, pruritus, urticaria and rash. **Periarteritis nodosa** and systemic lupus erythematosus have been reported. **Gastrointestinal:** Hepatitis (including cholestatic jaundice and hepatic necrosis), elevation of serum transaminase and bilirubin, pseudomembranous enterocolitis, pancreatitis, stomatitis, glossitis, nausea, emesis, abdominal pain, diarrhea, anorexia. **Genitourinary:** Renal failure, interstitial nephritis, BUN and serum creatinine elevation, toxic nephrosis with oliguria and anuria, crystalluria. **Neurologic:** Aseptic meningitis, convulsions, peripheral neuritis, ataxia, vertigo, tinnitus, headache. **Psychiatric:** Hallucinations, depression, apathy, nervousness. **Endocrine:** Sulfonamides bear certain chemical similarities to some goitrogens, diuretics (acetazolamide and the thiazides) and oral hypoglycemic agents; cross-sensitivity may exist. Ouresis and hypoglycemia have occurred rarely in patients receiving sulfonamides. **Musculoskeletal:** Arthralgia, myalgia. **Miscellaneous:** Weakness, fatigue, insomnia.

DOSAGE AND ADMINISTRATION: Not recommended for use in infants less than two months of age.

URINARY TRACT INFECTIONS AND SHIGELLOSIS IN ADULTS AND CHILDREN, AND ACUTE OTITIS MEDIA IN CHILDREN. Usual adult dosage for urinary tract infections is one DS tablet, two tablets or four teaspoonfuls (20 ml) b.i.d. for 10 to 14 days. Use identical daily dosage for 5 days for shigellosis. **Recommended dosage for children** with urinary tract infections or acute otitis media is 8 mg/kg trimethoprim and 40 mg/kg sulfamethoxazole per 24 hours, in two divided doses every 12 hours for 10 days. Use identical daily dosage for 5 days for shigellosis. **Renal Impaired:** Creatinine clearance above 30 ml/min, give usual dosage, 15-30 ml/min, give one-half the usual regimen; below 15 ml/min, use not recommended.

ACUTE EXACERBATIONS OF CHRONIC BRONCHITIS IN ADULTS: Usual adult dosage is one DS tablet, two tablets or four teasp. (20 ml) b.i.d. for 14 days.

PNEUMOCYSTIS CARINII PNEUMONITIS: Recommended dosage is 20 mg/kg trimethoprim and 100 mg/kg sulfamethoxazole per 24 hours in equal doses every 6 hours for 14 days. See complete product information for suggested children's dosage table.

HOW SUPPLIED: DS (double strength) Tablets (160 mg trimethoprim and 800 mg sulfamethoxazole)—bottles of 100, 250 and 500; Tel-E-Oose® packages of 100; Prescription Paks of 20. Tablets (80 mg trimethoprim and 400 mg sulfamethoxazole)—bottles of 100 and 500; Tel-E-Oose® packages of 100; Prescription Paks of 40. **Pediatric Suspension** (40 mg trimethoprim and 200 mg sulfamethoxazole per teasp.)—bottles of 100 ml and 16 oz (1 pint). **Suspension** (40 mg trimethoprim and 200 mg sulfamethoxazole per teasp.)—bottles of 16 oz (1 pint).

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For asymptomatic persons the Society recommends annual digital rectal examination at age 40 and over; at age 50 and over, an annual stool blood test, as well as sigmoidoscopy every three to five years, following two initial annual negative sigmoidoscopies.

We're here to help. You can reach us at your local American Cancer Society office or write to our Professional Education Department at National Headquarters, 90 Park Avenue, New York, N.Y. 10016. Ask about the Society's Colorectal Check program of professional and public education for the early detection of colorectal cancer.



*"Cancer of the Colon and Rectum: Summary of Public Attitude Survey," *Ca* 33:359-365, 1983 (Nov.-Dec.).

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References: 1. Feighner JP, et al. *Psychopharmacology* 61: 217-225, Mar 22, 1979. 2. Data on file, Hoffmann-La Roche Inc., Nutley, NJ

Limbitrol[®] Antidepressant

Before prescribing, please consult complete product information, a summary of which follows:

Indications: Relief of moderate to severe depression associated with moderate to severe anxiety

Contraindications: Known hypersensitivity to benzodiazepines or tricyclic antidepressants. Do not use with monoamine oxidase (MAO) inhibitors or within 14 days following discontinuation of MAO inhibitors since hyperpyretic crises, severe convulsions and deaths have occurred with concomitant use; then initiate cautiously, gradually increasing dosage until optimal response is achieved. Contraindicated during acute recovery phase following myocardial infarction.

Warnings: Use with great care in patients with history of urinary retention or angle-closure glaucoma. Severe constipation may occur in patients taking tricyclic antidepressants and anticholinergic-type drugs. Closely supervise cardiovascular patients (Arrhythmias, sinus tachycardia and prolongation of conduction time reported with use of tricyclic antidepressants, especially high doses. Myocardial infarction and stroke reported with use of this class of drugs.) Caution patients about possible combined effects with alcohol and other CNS depressants and against hazardous occupations requiring complete mental alertness (e.g., operating machinery, driving).

Use in Pregnancy: Use of minor tranquilizers during the first trimester should almost always be avoided because of increased risk of congenital malformations as suggested in several studies. Consider possibility of pregnancy when instituting therapy; advise patients to discuss therapy if they intend to or do become pregnant.

Since physical and psychological dependence to clordiazepoxide have been reported rarely, use caution in administering Limbitrol to addiction-prone individuals or those who might increase dosage, withdrawal symptoms following discontinuation of either component alone have been reported (nausea, headache and malaise for amitriptyline, symptoms [including convulsions] similar to those of barbiturate withdrawal for clordiazepoxide).

Precautions: Use with caution in patients with a history of seizures, in hyperthyroid patients or those on thyroid medication, and in patients with impaired renal or hepatic function. Because of the possibility of suicide in depressed patients, do not permit easy access to large quantities in these patients. Periodic liver function tests and blood counts are recommended during prolonged treatment. Amitriptyline component may block action of guanethidine or similar antihypertensives. When tricyclic antidepressants are used concomitantly with cimetidine (Tagamet), clinically significant effects have been reported involving delayed elimination and increasing steady state concentrations of the tricyclic drugs. Concomitant use of Limbitrol with other psychotropic drugs has not been evaluated, sedative effects may be additive. Discontinue several days before surgery. Limit concomitant administration of ECT to essential treatment. See Warnings for precautions about pregnancy. Limbitrol should not be taken during the nursing period. Not recommended in children under 12. In the elderly and debilitated, limit to smallest effective dosage to preclude ataxia, oversedation, confusion or anticholinergic effects.

Adverse Reactions: Most frequently reported are those associated with either component alone: drowsiness, dry mouth, constipation, blurred vision, dizziness and bloating. Less frequently occurring

reactions include vivid dreams, impotence, tremor, contusion and nasal congestion. Many depressive symptoms including anorexia, fatigue, weakness, restlessness and lethargy have been reported as side effects of both Limbitrol and amitriptyline. Granulocytopenia, jaundice and hepatic dysfunction have been observed rarely.

The following list includes adverse reactions not reported with Limbitrol but requiring consideration because they have been reported with one or both components or closely related drugs.

Cardiovascular: Hypotension, hypertension, tachycardia, palpitations, myocardial infarction, arrhythmias, heart block, stroke.

Psychiatric: Euphoria, apprehension, poor concentration, delusions, hallucinations, hypomania and increased or decreased libido.

Neurologic: Incoordination, ataxia, numbness, tingling and paresthesias of the extremities, extrapyramidal symptoms, syncope, changes in EEG patterns.

Anticholinergic: Disturbance of accommodation, paralytic ileus, urinary retention, dilatation of urinary tract.

Allergic: Skin rash, urticaria, photosensitization, edema of face and tongue, pruritus.

Hematologic: Bone marrow depression including agranulocytosis, eosinophilia, purpura, thrombocytopenia.

Gastrointestinal: Nausea, epigastric distress, vomiting, anorexia, stomatitis, peculiar taste, diarrhea, black tongue.

Endocrine: Testicular swelling and gynecomastia in the male, breast enlargement, galactorrhea and minor menstrual irregularities in the female, elevation and lowering of blood sugar levels, and syndrome of inappropriate ADH (antidiuretic hormone) secretion.

Other: Headache, weight gain or loss, increased perspiration, urinary frequency, mydriasis, jaundice, alopecia, parotid swelling.


Overdosage: Immediately hospitalize patient suspected of having taken an overdose. Treatment is symptomatic and supportive. IV administration of 1 to 3 mg physostigmine salicylate has been reported to reverse the symptoms of amitriptyline poisoning. See complete product information for manifestation and treatment.

Dosage: Individualize according to symptom severity and patient response. Reduce to smallest effective dosage when satisfactory response is obtained. Larger portion of daily dose may be taken at bedtime. Single h.s. dose may suffice for some patients. Lower dosages are recommended for the elderly. Limbitrol DS (double strength) Tablets, initial dosage of three or four tablets daily in divided doses, increased up to six tablets or decreased to two tablets daily as required. Limbitrol Tablets, initial dosage of three or four tablets daily in divided doses, for patients who do not tolerate higher doses.

How Supplied: Double strength (DS) Tablets, white, film-coated, each containing 10 mg clordiazepoxide and 25 mg amitriptyline (as the hydrochloride salt), and Tablets, blue, film-coated, each containing 5 mg clordiazepoxide and 12.5 mg amitriptyline (as the hydrochloride salt). Available in bottles of 100 and 500, Tel-E-Dose[®] packages of 100, Prescription Paks of 50.

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Please see summary of product information on adjacent page.

Alabama Medicine

February 1988

Vol. 57, No. 8

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See page 11

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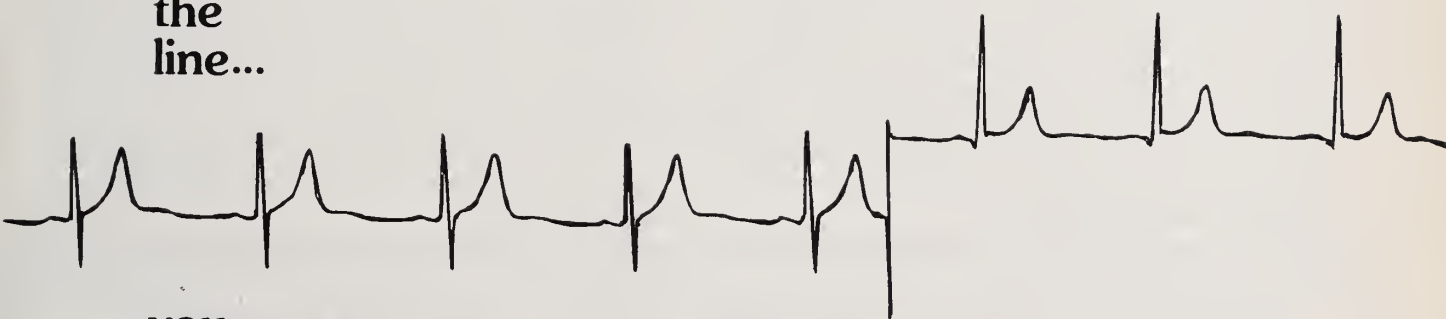
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HEIR TO A MISFORTUNE.



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Muscular Dystrophy Association, Jerry Lewis, National Chairman



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HYDROCODONE		X			X
CODEINE	X	X	X	X	X
OXYCODONE	XX	XX	XX	XX	XX

Blank space indicates that no such activity has been reported.

Table adapted from Facts and Comparisons (Nov.) 1984 and Catalano RB. The medical approach to management of pain caused by cancer. "Semin Oncol" 1975; 2; 379-92 and Reuler J8, et. al. The chronic pain syndrome: misconceptions and management. "Ann Intern Med" 1980; 93; 588-96.

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CONTRAINDICATIONS: Hypersensitivity to acetaminophen or hydrocodone.

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Respiratory Depression: At high doses or in sensitive patients, hydrocodone may produce dose-related respiratory depression by acting directly on brain stem respiratory centers. Hydrocodone also affects centers that control respiratory rhythm, and may produce irregular and periodic breathing.

Head Injury and Increased Intracranial Pressure: The respiratory depressant effects of narcotics and their capacity to elevate cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury, other intracranial lesions or a preexisting increase in intracranial pressure. Furthermore, narcotics produce adverse reactions which may obscure the clinical course of patients with head injuries.

Acute Abdominal Conditions: The administration of narcotics may obscure the diagnosis or clinical course of patients with acute abdominal conditions.

PRECAUTIONS:

Special Risk Patients: VICODIN should be used with caution in elderly or debilitated patients and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, prostatic hypertrophy or urethral stricture.

Information For Patients: VICODIN, like all narcotics, may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery; patients should be cautioned accordingly.

Cough Reflex: Hydrocodone suppresses the cough reflex; caution should be exercised when VICODIN is used postoperatively and in patients with pulmonary disease.

Drug Interactions: The CNS-depressant effects of VICODIN may be additive with that of other CNS depressants. When combined therapy is contemplated, the dose of one or both agents should be reduced. The use of MAO inhibitors or tricyclic antidepressants with hydrocodone preparations may increase the effect of either the antidepressant or hydrocodone. The concurrent use of anticholinergics with hydrocodone may produce paralytic ileus.

Usage in Pregnancy: Pregnancy Category C. Hydrocodone has been shown to be teratogenic in hamsters when given in doses 700 times the human dose. There are no adequate and well-controlled studies in pregnant women. VICODIN should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nonteratogenic Effects: Babies born to mothers who have been taking opioids regularly prior to delivery will be physically dependent. The intensity of the syndrome does not always correlate with the duration of maternal opioid use or dose.

Labor and Delivery: Administration of VICODIN to the mother shortly before delivery may result in some degree of respiratory depression in the newborn, especially if higher doses are used.

Nursing Mothers: It is not known whether this drug is excreted in human milk; therefore, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS:

Central Nervous System: Sedation, drowsiness, mental clouding, lethargy, impairment of mental and physical performance, anxiety, fear, dysphoria, dizziness, psychic dependence, mood changes.

Gastrointestinal System: Nausea and vomiting may occur; they are more frequent in ambulatory than in recumbent patients. Prolonged administration of VICODIN may produce constipation.

Genitourinary System: Ureteral spasm, spasm of vesical sphincters and urinary retention have been reported.

Respiratory Depression: (See WARNINGS.)

DOSAGE AND ADMINISTRATION: Dosage should be adjusted according to the severity of the pain and the response of the patient. However, tolerance to hydrocodone can develop with continued use, and the incidence of untoward effects is dose related.

The usual dose is one tablet every six hours as needed for pain. (If necessary, this dose may be repeated at four-hour intervals.) In cases of more severe pain, two tablets every six hours (up to eight tablets in 24 hours) may be required.

Revised, April 1982.

5685

1. Hopkinson JH III: *Curr Ther Res* 24: 503-516, 1978

2. Beaver, WT *Arch Intern Med*, 141:293-300, 1981.

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EXECUTIVE DIRECTOR



S. Lon Conner
Executive Director, MASA

Playing God

ON THE FIRST SUNDAY of 1988, two television commentators were discussing the newly allowable 65 mph speed limits on the interstate system.

Congress had again liberalized it in the blizzard of measures passed in the latest travesty on constitutional government, the continuing resolution enacted a couple of days before Christmas. That was yet another branch of the infamous Jukes family of congressional monstrosities already producing OBRA, COBRA and SOBRA.

Sam Donaldson, one of the contenders, was holding forth on the idea that allowing the speed limit to be raised from 55 to 65 was a conscious decision by the nation to trade several thousand lives a year for public convenience.

George Will responded by positing a question: if lives saved should be the only consideration, why not lower the speed limit to, say, 35 miles an hour or even

15, because even more thousands would be saved at lower and lower speeds.

Donaldson, walking into Will's trap, said there is a practical minimum speed beneath which it would be silly to go — even if more lives were saved.

Will sprung his trap: then you are making the same trade-off of convenience for lives that you accuse others of doing above 55.

And he was absolutely right. The Ford motor company was pilloried in public some years ago for deciding that the Pinto's gas tank location posed only a limited hazard, with predicted mortality at the "acceptable" level. Ford was accused by trial lawyers in the famous Pinto case of playing God with lives. And the jury was suitably impressed.

Of course the nation does this all the time; we are certainly doing it in allowing the 55 mph limit to be raised, since we know with something like mathe-

matical certainty how many more Americans will die as speed increases. And we are doing it in *not* reducing the maximum legal speed to 35 or 25. We make a conscious or unconscious decision to trade-off a certain number of our fellow Americans' lives for the convenience and perhaps necessity of the hurried majority.

Designers of commercial aircraft do it when they conceive a new airliner. The public is generally unaware of the trade-offs made in the selection of materials and in the structural integrity of the airframe. A plane could be made much more crash resistant but at an ever increasing weight penalty, which would itself become a safety factor as well as a cost factor. Jet fuel is expensive. More weight requires more fuel. It is quite possible to make a modern aircraft cabin that would be virtually crush-proof and fire-proof. But the plane simply would not fly.

So trade-offs are made in just about everything, and the trade-off is usually the public's convenience and necessity on one side and lives on the other. The balancing act is quite deliberate although usually unspoken.

What I am leading up to should be obvious: the critical choices society must make — is, in fact, already making — in the allocation of increasingly scarce health care resources. HCFA's current ratcheting down on the quantity and intensity of care of Americans is a calculated balancing act not unlike that practiced by the designers of aircraft and automobiles. For example, HCFA surely knows that a certain number of Americans will be forfeited by each new constriction on the definition of "medical necessity." If an attending physician can't be certain that his patient can safely be discharged when the DRG limit is reached, you may be sure that no distant bureaucracy can begin to assess that risk. But it *can* assess the risk in the cold logic of deaths per 100,000 patients.

It would be my guess that, with its vast computer capacity, HCFA has a war room where very hush-hush mortality projections are made to accompany each proposed new reduction in the intensity of care. Just as the National Safety Council has an uncanny record of predicting holiday traffic deaths, so I believe does HCFA know what the mortality price might be for every turn of the screw.

In doing so, HCFA is not being ruthlessly irresponsible: it is trying to allocate inadequate resources to achieve the Jeffersonian ideal of the greatest good to the greatest number. Blame must be shifted to Congress, which refuses to adequately fund its promises to the American people. But beyond Congress, the people themselves make the final decision, by balking at new revenues and sending that message to their representatives. Rationing begins with limitations imposed on resources. So we all share responsibility.

The trade-offs will become more and more public, however, as we move into the brave new world of

ever more miraculous (and exorbitantly expensive) medical technology on the one hand and greater demands upon limited resources on the other. As the number of the elderly increases, the relative number of younger taxpayers is decreasing. It would be bad enough if all those expensive technologies had not occurred at this time in national history, but they are there and people want them.

Denying ultimate care is difficult in this country which professes to place human life as worth any cost. The gap between that contention and its practical application at bedside is widening. In the immediate future, the gap will become a gulf. The national debate will not be limited to who should be favored with transplants, dialysis, heart repair and the rest. It will take in the whole of our national purpose in the fields of therapy, prevention and public safety.

In a wide-ranging paper presented some months ago to the Geneva Association, Dr. Milton C. Weinstein, Professor of Policy and Decision Sciences of the Harvard School of Public Health, provides a glimpse at that future, which is already here.

Dr. Weinstein's essay, "Risky Choices in Medical Decision Making: A Survey," suggests that physicians of the future will use computer software to weigh decisions but that "budgetary constraints [will] limit [the] health care provider in the same way that the classical economic consumer is limited by his or her income."

Application of the principles of decision analysis, derived from what is called the "theory of decision-making under uncertainty," is already far advanced in business administration and has made significant invasions into clinical medicine. Dr. Weinstein expects these to increase and offers the view that decision analysis in medicine is as plausible as in answering such questions as "whether and where to drill for oil." He expects physicians of the future to have personal computers at bedside to assist them in answering very tough questions involving the granting and withholding of technology. (It is well that George Orwell has already gone to his reward.)

But this column is on the larger public choices we face as a nation. Dr. Weinstein presents a table based on recent studies showing "the cost per year of life saved" for some health investments our society is already making. At the most cost effective end (defined, again, as the cost per year of life saved) is the mandatory air bag. Studies indicate that it would cost just \$540 per year for every year of life saved. Mandatory smoke detectors in bedrooms of the nation are almost as good a national buy: costing only \$1,300 for every year of life saved. The Motor Vehicle Safety Act of 1966 is still a bargain at \$6,300 per year of life saved, as is coronary artery bypass (three vessel) at \$7,200.

Next in relatively cost effective investments was the 55 mph speed limit (Dr. Weinstein presented the paper before Congress relaxed the rules), which bought a

year of life for \$12,000.

But then the table takes a big jump: hemodialysis costs more than twice as much per year of life saved, \$25,000, as the 55 mph speed limit did. Air pollution controls cost \$105,000; prevention of water carcinogens, \$240,000; liver transplants \$250,000; limitation of vinyl chloride to one part per million, \$490,000 per year of life saved; and limitation of benzene to the one part per million occupational standard costs as incredible \$6.6 million per year of life saved.

Now many of us would quickly say let's save that money on benzene elimination and use it somewhere else, but we might not if we were workers, few though they are, threatened by this very real hazard to their lives. Or we might say that we would trade the cost of just one liver transplant for 10 dialysis allocations but only if we were dialysis patients or their families, not the mother of a child whose fate hangs on getting a new liver.

This is only the very beginning of the terrible choices facing the nation in its allocation of shrinking resources. We can't have everything; life cannot be made 100% secure. Most Americans will agree on that. Beyond that, however, almost nothing is easy, as we are forced to choose, quite literally, who shall live and who shall die.

Nobody wants to play God in this way. But the nation has already begun doing just that — in parceling out rationed medical care for its elderly, a movement being imitated by private-sector third-party payers. And the rationing of resources has only just begun.

It is not a happy thought for the last years of the 20th century. But the questions must inevitably be faced, with increasing difficulty and pain. •

Lon



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1. For therapeutic use in patients with hypokalemia with or without metabolic alkalosis, in digitalis intoxication and in patients with hypokalemic familial periodic paralysis.

2. For the prevention of potassium depletion when the dietary intake is inadequate in the following conditions: Patients receiving digitalis and diuretics for congestive heart failure, hepatic cirrhosis with ascites, states of aldosterone excess with normal renal function, potassium-losing nephropathy, and with certain diarrheal states.

3. The use of potassium salts in patients receiving diuretics for uncomplicated essential hypertension is often unnecessary when such patients have a normal dietary pattern. Serum potassium should be checked periodically, however, and if hypokalemia occurs, dietary supplementation with potassium-containing foods may be adequate to control milder cases. In more severe cases supplementation with potassium salts may be indicated.

CONTRAINDICATIONS: Potassium supplements are contraindicated in patients with hyperkalemia since a further increase in serum potassium concentration in such patients can produce cardiac arrest. Hyperkalemia may complicate any of the following conditions: Chronic renal failure, systemic acidosis such as diabetic acidosis, acute dehydration, extensive tissue breakdown as in severe burns, adrenal insufficiency, or the administration of a potassium-sparing diuretic (e.g., spironolactone, triamterene).

Wax-matrix potassium chloride preparations have produced esophageal ulceration in certain cardiac patients with esophageal compression due to enlarged left atrium.

All solid dosage forms of potassium chloride supplements are contraindicated in any patient in whom there is cause for arrest or delay in tablet passage through the gastrointestinal tract. In these instances, potassium supplementation should be with a liquid preparation.

WARNINGS: Hyperkalemia—In patients with impaired mechanisms for excreting potassium, the administration of potassium salts can produce hyperkalemia and cardiac arrest. This occurs most commonly in patients given potassium by the intravenous route but may also occur in patients given potassium orally. Potentially fatal hyperkalemia can develop rapidly and be asymptomatic. The use of potassium salts in patients with chronic renal disease, or any other condition which impairs potassium excretion, requires particularly careful monitoring of the serum potassium concentration and appropriate dosage adjustment.

Interaction with Potassium-Sparing Diuretics—Hypokalemia should not be treated by the concomitant administration of potassium salts and a potassium-sparing diuretic (e.g., spironolactone or triamterene) since the simultaneous administration of these agents can produce severe hyperkalemia.

Gastrointestinal Lesions—Potassium chloride tablets have produced stenotic and/or ulcerative lesions of the small bowel and deaths. These lesions are caused by a high localized concentration of potassium ion in the region of a rapidly dissolving tablet, which injures the bowel wall and thereby produces obstruction, hemorrhage or perforation.

K-DUR tablets contain micro-crystalloids which disperse upon disintegration of the tablet. These micro-crystalloids are formulated to provide a controlled release of potassium chloride. The dispersibility of the micro-crystalloids and the controlled release of ions from them are intended to minimize the possibility of a high local concentration near the gastrointestinal mucosa and the ability of the KCl to cause stenosis or ulceration. Other means of accomplishing this (e.g., incorporation of potassium chloride into a wax matrix) have reduced the frequency of such lesions to less than one per 100,000 patient years (compared to 40-50 per 100,000 patient years with enteric-coated potassium chloride) but have not eliminated them. The frequency of GI lesions with K-DUR tablets is, at present, unknown. K-DUR tablets should be discontinued immediately and the possibility of bowel obstruction or perforation considered if severe vomiting, abdominal pain, distention, or gastrointestinal bleeding occurs.

Metabolic Acidosis—Hypokalemia in patients with metabolic acidosis should be treated with an alkalinizing potassium salt such as potassium bicarbonate, potassium citrate, potassium acetate, or potassium gluconate.

PRECAUTIONS: The diagnosis of potassium depletion is ordinarily made by demonstrating hypokalemia in a patient with a clinical history suggesting some cause for potassium depletion. In interpreting the serum potassium level, the physician should bear in mind that acute alkalosis per se can produce hypokalemia in the absence of a deficit in total body potassium while acute acidosis per se can increase the serum potassium concentration into the normal range even in the presence of a reduced total body potassium. The treatment of potassium depletion, particularly in the presence of cardiac disease, renal disease, or acidosis requires careful attention to acid-base balance and appropriate monitoring of serum electrolytes, the electrocardiogram, and the clinical status of the patient.

Laboratory Tests: Regular serum potassium determinations are recommended. In addition, during the treatment of potassium depletion, careful attention should be paid to acid-base balance, other serum electrolyte levels, the electrocardiogram, and the clinical status of the patient, particularly in the presence of cardiac disease, renal disease, or acidosis.

Drug Interactions: Potassium-sparing diuretics; see **WARNINGS**.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term carcinogenicity studies in animals have not been performed.

Pregnancy Category C: Animal reproduction studies have not been conducted with K-DUR. It is also not known whether K-DUR can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. K-DUR should be given to a pregnant woman only if clearly needed.

Nursing Mothers: The normal potassium ion content of human milk is about 13 mEq per liter. Since oral potassium becomes part of the body potassium pool, so long as body potassium is not excessive, the contribution of potassium chloride supplementation should have little or no effect on the level in human milk.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: One of the most severe adverse effects is hyperkalemia (see **CONTRAINDICATIONS, WARNINGS, and OVERDOSAGE**). There have also been reports of upper and lower gastrointestinal conditions including obstruction, bleeding, ulceration, and perforation (see **CONTRAINDICATIONS and WARNINGS**); other factors known to be associated with such conditions were present in many of these patients.

The most common adverse reactions to oral potassium salts are nausea, vomiting, abdominal discomfort, and diarrhea. These symptoms are due to irritation of the gastrointestinal tract and are best managed by taking the dose with meals or reducing the dose.

Skin rash has been reported rarely.

OVERDOSAGE: The administration of oral potassium salts to persons with normal excretory mechanisms for potassium rarely causes serious hyperkalemia. However, if excretory mechanisms are impaired or if potassium is administered too rapidly intravenously, potentially fatal hyperkalemia can result (see **CONTRAINDICATIONS and WARNINGS**). It is important to recognize that hyperkalemia is usually asymptomatic and may be manifested only by an increased serum potassium concentration and characteristic electrocardiographic changes (peaking of T-waves, loss of P-waves, depression of S-T segment, and prolongation of the QT-interval). Late manifestations include muscle-paralysis and cardiovascular collapse from cardiac arrest.

Treatment measures for hyperkalemia include the following:

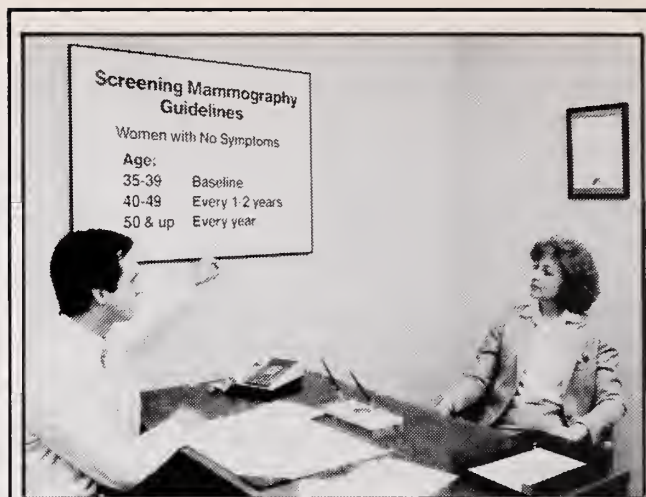
1. Elimination of foods and medications containing potassium and of potassium-sparing diuretics.
2. Intravenous administration of 300 to 500 ml/hr of 10% dextrose solution containing 10-20 units of insulin per 1,000 ml.
3. Correction of acidosis, if present, with intravenous sodium bicarbonate.
4. Use of exchange resins, hemodialysis, or peritoneal dialysis.

In treating hyperkalemia, it should be recalled that in patients who have been stabilized on digitalis, too rapid a lowering of the serum potassium concentration can produce digitalis toxicity.

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PRESIDENT'S PAGE



*Carl A. Grote, Jr., M.D.
President, MASA*

Playing HCFA's Dungeons and Dragons

As one starts into a new year he cannot help but look back and then forward. As I look back over 1987 one of the most frustrating things that had happened to me was my dealings, both voluntary and involuntary, with Medicare and Medicaid.

My dealings with the Feds has had to do with the Medicare and Medicaid programs. When the participating/non-participating programs first began, my partner and I sat down to try and figure which would be best for us and which would be best for our patients.

We came to the conclusion that it would be fairer to all for us to participate in the Medicare program. What followed was a year of frustration, both on our

part and on the part of the patients. Patients didn't understand the program and we didn't understand the program. And, to say the least, it was less than financially rewarding.

The patients who came to our office had been coming here for years; they did not understand why they could not pay their bills. They also did not understand that when there was a balance left over that they should not pay this.

We received many checks in the mail that we had to simply return. The bookkeeping was a nightmare. For those of you who have only a few Medicare patients in your practice this may not seem to be a big

deal. But when you've been in practice for over 30 years the age of your patients begins to get older and Medicare patients make up a sizable part of your practice. This is added to by the fact that I took over a practice from my father, which was made up of elderly patients even at that time.

The phone rang constantly with patients asking questions about their statements: either why the amounts that were shown were there or why they didn't receive a statement, etc., etc.

After a very frustrating year to me, my patients, and most of all my office personnel, my partner and I once again sat down and reconsidered the whole matter. After a year of participating we decided that it was wise to become non-participating again.

After becoming non-participating a breath of fresh air seemed to go through our office. The patients seemed to be happier to go back to the old way of doing and certainly my office personnel was. We had already come to grips with the fact that we would have to charge different prices for the Medicare patients than we did for other people in our practice.

This was no big deal even though a good number of the elderly patients that I have are more than able to pay; in fact, some of them are more able to pay than the younger patients. But be that as it may, we cruised along.

During the next year something came out called MAAC. We received some communications about it from HCFA, as from Blue Cross/Blue Shield, and tried to pore over this. A formula was included on several occasions which told us how to figure what our maximum allowable charge should be. We could not make heads or tails of this.

We were furnished with some figures but these were the area prevailing fees. We went along our merry way having no doubt that we were in compliance with every law and every rule and regulation, doing our best with them.

In November we began to understand the MAAC program much better. We received a notification from HCFA through Blue Cross/Blue Shield that we were not in compliance with the law. For the first time we were told what our maximum allowable charges were.

That is, we were told after we were able to get the representative from Blue Cross/Blue Shield to bring those charges to our office. The communication also stated that we must bring these charges into compliance or be turned over to the Inspector General of the United States.

I am sure that many of you have had similar experiences and probably even worse. I think that the frustration over all of this is in trying to deal with the system. It is hard to understand the communications that you receive even if you're trying to. It is hard to find anyone you can talk to. It is hard to find someone

who can give you the correct answers even if they are willing to talk to you.

Some time the information that you need is not even available. For instance, all of us were supposed to decide whether we would be participating or non-participating for the coming year by January 1. But as all of you well know, you were not furnished enough information to make the proper decisions. That is, you are not furnished with the MAAC for the coming year. You are not furnished with what the usual and customary fees were for the area and it has not been decided as of yet how much the cuts in the fees would be.

Another anecdotal experience that I had a few months ago with the Feds came after I had attended a nursing home patient whom I had known and treated over a number of years. He was confined because of Alzheimer's Disease and was completely out of touch with reality.

I went to the nursing home at the request of the nurse there because he was running a high fever, his blood pressure was down, etc. I saw him three times over the next three days and finally the patient expired.

When I sent in a charge on Medicare, I received a letter stating that the charge was not allowable and that furthermore I could not charge the patient; if I had charged him I must refund the money. I am sure many of you have received similar letters. After writing and calling several people, I finally received a letter through Blue Cross/Blue Shield saying that they would allow me to charge the patient \$18 for each of the visits.

How they arrived at this is known only to someone locked in the bounds of Blue Cross/Blue Shield or some other such impenetrable fortress. In spite of my continuing to inquire as to how they arrived at this, I have not received a satisfactory answer. It seems that someone, somewhere just decided that that was what they would pay.

I am upset, I am frustrated, I am infuriated. HCFA through Blue Cross/Blue Shield has done everything that they would put you and me in jail for. They have fixed prices. They have coerced. They have discriminated. I have no doubt that it is Bill Roper's intent that every one will participate in one way or another. I think that the terms of being participating and non-participating are archaic. We are all participating in one way or another and he is seeing to that.

Arbitrary decisions are made both by the federal agent and by the fiscal intermediary. Now what to do? This is the frustrating part. It is hard to know how to proceed to make any real impact with these people. I have no doubt that changes are on the way which will make the ones that have already occurred look like child's play.

Some way we need to make the people in Washington understand that we are not just a bunch of money-

grubbing practitioners trying to line our own pockets. We need to make them understand that this is affecting the quality of care patients are receiving.

They need to understand that we as practitioners are willing to work within the system and are willing to try to conserve the resources that are available. However, they cannot legislate or dictate from a thousand miles away the care of an individual patient.

So far the AMA has been unable or unwilling to make any impact on Congress. I do not think that our senators and representatives will heed anything until it comes from the people themselves. I think we as

practitioners will have to continue to talk to our patients and encourage them to write at every opportunity to those in Washington.

Just maybe, if the mail becomes heavy enough from home, they will begin to listen and find out what is going on. If they expect first-class care, then they are going to have to pay for it. □

Carl

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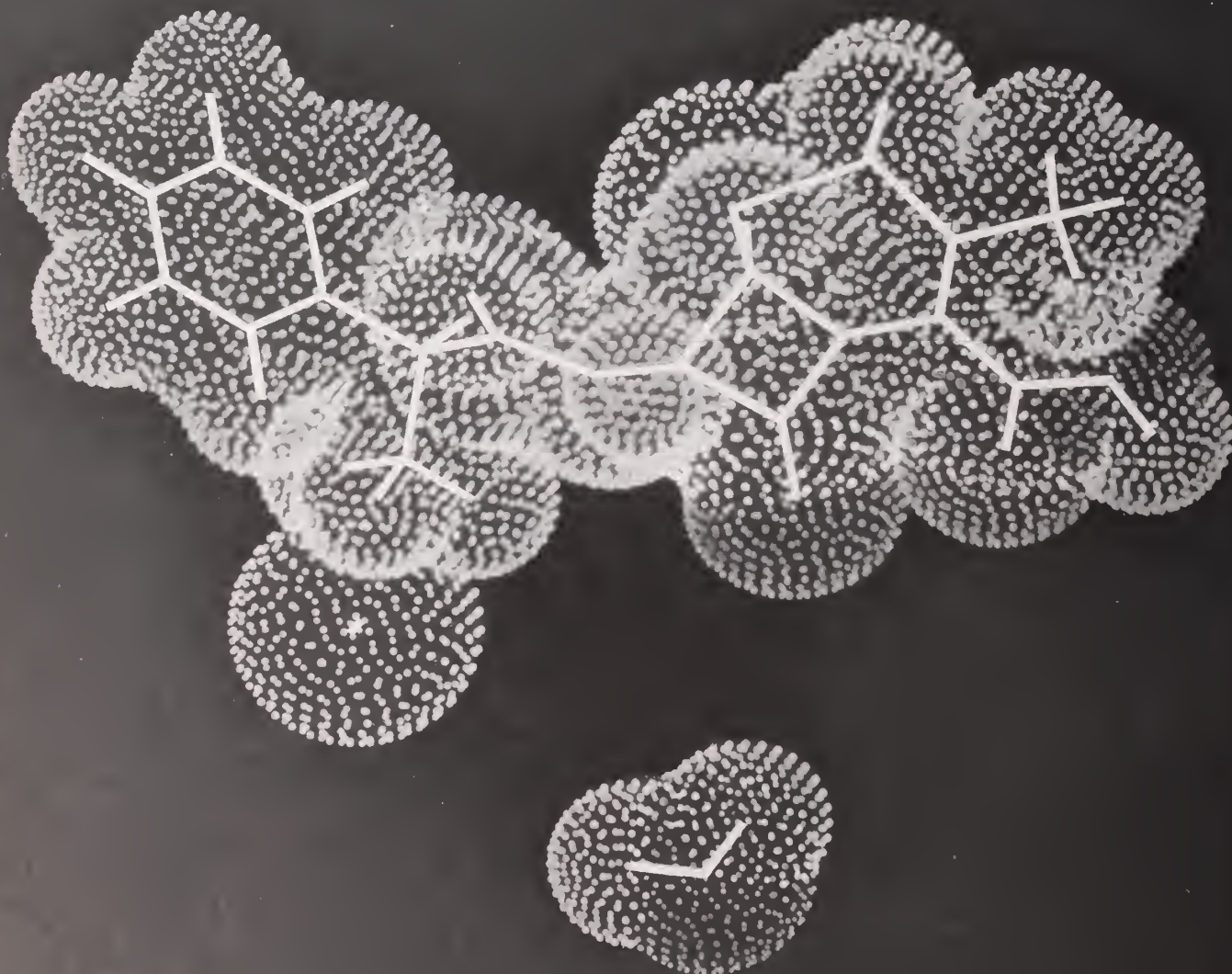


ANNOUNCING

NEW

KEFTABTM

cephalexin hydrochloride monohydrate



Dista Products Company
Division of Eli Lilly and Company
Indianapolis, Indiana 46285
Mfd by Eli Lilly Industries, Inc
Carolina, Puerto Rico 00630

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Computer-generated molecular
structure of cephalexin
hydrochloride monohydrate

Convenient 500-mg b.i.d. dosage and demonstrated effectiveness for treatment of:

- skin and skin structure infections*
- uncomplicated cystitis[†]
- pharyngitis[‡]

- New hydrochloride salt form of cephalexin—requires no conversion in the stomach before absorption
- Well-tolerated therapy
- May be taken without regard to meals



For other indicated infections, 250-mg tablets available for q.i.d. dosage

Priced less than Keflex[®] (cephalexin)

Keftab is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillin-sensitive patients.

Penicillin is the drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever.

*Due to susceptible strains of *Staphylococcus aureus* and/or β -hemolytic streptococci.

[†]Due to susceptible strains of *Escherichia coli*, *Proteus mirabilis*, and *Klebsiella* sp.

[‡]Due to susceptible strains of group A β -hemolytic streptococci.

KEFTAB™

(cephalexin hydrochloride monohydrate)

Summary: Consult the package literature for prescribing information.

Indications and Usage:

Respiratory tract infections caused by susceptible strains of *Streptococcus pneumoniae* and group A β -hemolytic streptococci.

Skin and skin structure infections caused by susceptible strains of *Staphylococcus aureus* and/or β -hemolytic streptococci.

Bone infections caused by susceptible strains of *S aureus* and/or *Proteus mirabilis*.

Genitourinary tract infections, including acute prostatitis, caused by susceptible strains of *Escherichia coli*, *P mirabilis*, and *Klebsiella* sp.

Contraindication: Known allergy to cephalosporins.

Warnings: KEFTAB SHOULD BE ADMINISTERED CAUTIOUSLY TO PENICILLIN-SENSITIVE PATIENTS. PENICILLINS AND CEPHALOSPORINS SHOW PARTIAL CROSS-ALLERGENICITY. POSSIBLE REACTIONS INCLUDE ANAPHYLAXIS.

Administer cautiously to allergic patients.

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics. It must be considered in differential diagnosis of antibiotic-associated diarrhea. Colon flora is altered by broad-spectrum antibiotic treatment, possibly resulting in antibiotic-associated colitis.

Precautions:

- Discontinue Keftab in the event of allergic reactions to it.
- Prolonged use may result in overgrowth of nonsusceptible organisms.
- Positive direct Coombs' tests have been reported during treatment with cephalosporins.
- Keftab should be administered cautiously in the presence of markedly impaired renal function. Although dosage adjustments in moderate to severe renal impairment are usually not required, careful clinical observation and laboratory studies should be made.
- Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.
- Safety and effectiveness have not been determined in pregnancy and lactation. Cephalexin is excreted in mother's milk. Exercise caution in prescribing Keftab for these patients.
- Safety and effectiveness in children have not been established.

Adverse Reactions:

- *Gastrointestinal*, including diarrhea and, rarely, nausea and vomiting. Transient hepatitis and cholestatic jaundice have been reported rarely.
- *Hypersensitivity* in the form of rash, urticaria, angioedema, and, rarely, erythema multiforme, Stevens-Johnson syndrome, or toxic epidermal necrolysis.
- *Anaphylaxis* has been reported.
- *Other reactions* have included genital/anal pruritus, genital moniliasis, vaginitis/vaginal discharge, dizziness, fatigue, headache, eosinophilia, neutropenia, and thrombocytopenia; reversible interstitial nephritis has been reported rarely.
- Cephalosporins have been implicated in triggering seizures, particularly in patients with renal impairment.
- *Abnormalities in laboratory test results* included slight elevations in aspartate aminotransferase (AST, SGOT) and alanine aminotransferase (ALT, SGPT). False-positive reactions for glucose in the urine may occur with Benedict's or Fehling's solution and Clinitest[®] tablets but not with Tes-Tape[®] (Glucose Enzymatic Test Strip, USP, Lilly).

Hypophosphatemia in Critically Ill Pulmonary Patients

Rama L. R. Nandipati, M.D.*

Staff Physician

Nageswara R. Chava, M.D.; F.A.C.P.

Chief, Medical Service

Abstract

Low serum phosphate levels are recognized with increasing frequency in hospitalized patients and severe hypophosphatemia is often associated with multisystem dysfunction. We retrospectively reviewed the charts of 42 patients with 43 admissions to Intensive Care Unit (ICU) over one year period with a respiratory diagnosis. The overall prevalence of low serum phosphate levels, i.e. serum phosphate level less than 2.4 mg/dL, was 37 percent, 57 percent in those with bacterial pneumonia, and 18 percent in those without pneumonia. Since phosphate plays a major role in oxygen transport, cellular metabolism and leukocyte function, recognition of hypophosphatemia and maintenance of normal serum phosphate level is essential to treat patients with respiratory illness.

The prevalence of hypophosphatemia in hospitalized patients is reported to be about 2 to 3 percent, whereas in patients withdrawing from alcohol, treatment of diabetic acidosis, intravenous dextrose infusion, nutritional recovery, and respiratory infections, the prevalence of hypophosphatemia ranges from 20 to 40 percent.¹

Hypophosphatemia adversely affects patients with respiratory illness, since low serum phosphate levels are implicated in precipitating respiratory failure, decreased diaphragmatic contractility, failed weaning, impaired oxygen delivery to tissues, leukocyte dysfunction, and prolonged hospital stay.

Methods

Eighty-three patients admitted to ICU over a one year period with a diagnosis of respiratory illness (chronic obstructive lung disease, respiratory failure, respiratory arrest, asthmatic bronchitis, pneumonia) were considered for this review. The charts of 42 patients with 43 admissions with at least one serum phosphate determination either during ICU stay or within one week prior to ICU admission were reviewed. Hypophosphatemia was defined as at least one value less

* Medical Service, V.A. Medical Center, 215 Perry Hill Road, Montgomery, AL 36193. Dr. Nandipati is now a Pulmonary Fellow at Mt. Siani Services, City Hospital Center at Elmhurst, New York.

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Perhaps you are thinking of adding to your practice and would like:

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- A partner until you are ready to retire.

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Frank Cochran

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- Someone to act as your agent.

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Hypophosphatemia

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than 2.4 mg/dL. For patients with multiple episodes of hypophosphatemia, the lowest serum phosphate level was recorded.

The admissions were divided into 4 groups: Group 1, low serum phosphate with bacterial pneumonia (No = 12); Group 2, low serum phosphate without pneumonia (No = 4); Group 3, normal serum phosphate with bacterial pneumonia (No = 9); Group 4, normal serum phosphate without pneumonia (No = 18).

Results

The overall prevalence of hypophosphatemia in the patients with respiratory diagnosis admitted to ICU was 37 percent, 57 percent in those with bacterial pneumonia and 18 percent in those without pneumonia. Conversely, among the 16 admissions with low serum phosphate levels, 12 (75 percent) had pneumonia, compared with 27 admissions with normal serum phosphate levels in whom 9 (33 percent) had pneumonia.

Serum phosphate levels were as follows: Group 1, 1.45 ± 0.85 ; Group 2, 1.7 ± 0.4 ; Group 3, 3.65 ± 1.05 ; Group 4, 4.05 ± 1.65 . Four patients in Group 1 and none in other groups had serum phosphate levels ≤ 1.0 mg/dL.

Discussion

Our retrospective review of patients with respiratory illness admitted to ICU demonstrated high prevalence of hypophosphatemia (37 percent), specifically, in patients with bacterial pneumonia (57 percent). Commonly observed causative factors were alcoholism, antacids, and poor nutritional status.

Clinical Situations Associated with Hypophosphatemia

Hypophosphatemia may be seen in a variety of clinical situations as described in table 1.^{2,3}

Pathogenesis

Hypophosphatemia with or without phosphate depletion may result from decreased dietary intake and reduced intestinal absorption, increased losses via renal or gastrointestinal pathways, and transcellular shifts of phosphate ion.

One or more of the above mentioned mechanisms of production of hypophosphatemia or clinical situations, specifically, respiratory infections, respiratory alkalosis, phosphate binding antacids, dextrose infusion, and steroid administration may play a role in the development of low serum phosphate levels in patients with respiratory illness.

Clinical Manifestations

Severe hypophosphatemia (serum phosphate < 1 mg/dL) often results in multisystem dysfunction, which include reversible myocardial dysfunction, acute respiratory failure, metabolic encephalopathy, muscular weakness, paresthesias, hyporeflexia, overt proximal myopathy, rhabdomyolysis, hemolytic anemia, reductions in erythrocyte ATP and 2,3-DPG, diminished chemotactic, phagocytic and bactericidal activity, platelet dysfunction, glucose intolerance, reduced parathyroid gland function, and renal tubular acidosis.

Effect of Hypophosphatemia on Respiratory Illness

Hypophosphatemia, with its well documented deleterious effects on neuromuscular, erythrocyte, and leukocyte functions, precipitates and sustains respiratory failure and infectious respiratory illness.

Acute respiratory failure associated with hypophosphatemia and responding to administration of inorganic phosphate has been described.⁴ Augusti et al⁵

TABLE 1

Clinical situations associated with hypophosphatemia

Profound Hypophosphatemia
Diabetic Ketoacidosis
Alcoholism
Phosphate binding antacids
Severe burns
Hyperalimentation with phosphate deficient preparations
Nutritional recovery syndrome
Severe respiratory alkalosis
Moderate Hypophosphatemia
Gram Negative Sepsis
Infectious Respiratory Illness
Poor intake, Vomiting
Chronic diarrhea, Malabsorption
Administration of
Dextrose, Fructose, Lactate, Glycerol
Saline, Sodium bicarbonate
Insulin, Glucagon, Corticosteroids,
Epinephrine, Gastrin, Androgens
Diuretic therapy
Hypokalemia, Hypomagnesemia
Vitamin D deficiency
Pregnancy
Acute gout
Salicylate poisoning
Hyperparathyroidism, "Hungry bone syndrome"
Osteomalacia
Thyrotoxic periodic paralysis
Acidemia
Renal tubular defects, Hemodialysis, Renal grafts
Recovery from hypothermia
T-Cell lymphoblastic lymphoma
Histiocytic lymphoma

continued on page 20

**"Why don't you call us
in a month or so?"**

"Sorry, we're not hiring right now."

**"We'll call you when
something opens up."**

**"Why don't you leave your number
and we'll get back to you."**

**"We'll keep you
in mind."**

**"If only you had a little more
experience."**



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Hypophosphatemia

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reported a case describing a relationship between the patient's serum phosphate level and the maximal inspiratory pressure. In their patient, weaning was not possible until phosphate depletion was corrected with resultant increase in maximal inspiratory pressure. The contractile properties of the diaphragm during acute respiratory failure was impaired by hypophosphatemia.⁶

Travis et al⁷ induced hypophosphatemia in five adult patients and demonstrated reduction in erythrocyte 2,3-DPG and ATP accompanied by a striking increase in red blood cells' affinity for oxygen. Increased red cell affinity for oxygen leads to impaired oxygen delivery and tissue hypoxia.

Depression of chemotactic, phagocytic and bactericidal activity of the granulocytes was demonstrated in dogs with concomitant reduction in leukocyte ATP level.⁸ Similar observations were made by these investigators on a single patient who became hypophosphatemic during hyperalimentation.

In a review of 308 admissions to a pulmonary disease ward, Fisher et al¹ reported that although mortality was no higher in hypophosphatemic patients, hospital stay was twice as long as that of patients with normal levels of serum phosphate.

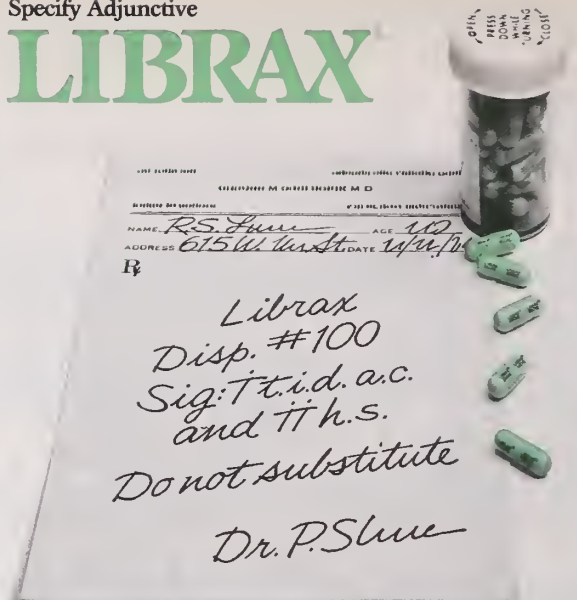
In summary, our study reproduces previously observed high prevalence of hypophosphatemia in patients with respiratory illness, specifically, infectious respiratory illness. In view of the deleterious effects of hypophosphatemia in such patients, it is essential to recognize hypophosphatemia, replace phosphate when indicated, and closely monitor replacement therapy. □

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Specify Adjunctive

LIBRAX



Each capsule contains 5 mg chlordiazepoxide HCl and 2.5 mg clidinium bromide

Please consult complete prescribing information, a summary of which follows:

- * **Indications:** Based on a review of this drug by the National Academy of Sciences—National Research Council and/or other information, FDA has classified the indications as follows: "Possibly" effective: as adjunctive therapy in the treatment of peptic ulcer and in the treatment of the irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis. Final classification of the less-than-effective indications requires further investigation.

Contraindications: Glaucoma; prostatic hypertrophy, benign bladder neck obstruction; hypersensitivity to chlordiazepoxide HCl and/or clidinium Br.

Warnings: Caution patients about possible combined effects with alcohol and other CNS depressants, and against hazardous occupations requiring complete mental alertness (e.g., operating machinery, driving). Physical and psychological dependence rarely reported on recommended doses, but use caution in administering Librium® (chlordiazepoxide HCl/Roche) to known addiction-prone individuals or those who might increase dosage; withdrawal symptoms (including convulsions) reported following discontinuation of the drug.

Usage in Pregnancy: Use of minor tranquilizers during first trimester should almost always be avoided because of increased risk of congenital malformations as suggested in several studies. Consider possibility of pregnancy when instituting therapy. Advise patients to discuss therapy if they intend to or do become pregnant.

As with all anticholinergics, inhibition of lactation may occur. **Precautions:** In elderly and debilitated, limit dosage to smallest effective amount to preclude ataxia, oversedation, confusion (no more than 2 capsules/day initially; increase gradually as needed and tolerated). Though generally not recommended, if combination therapy with other psychotropics seems indicated, carefully consider pharmacology of agents, particularly potentiating drugs such as MAO inhibitors, phenothiazines. Observe usual precautions in presence of impaired renal or hepatic function. Paradoxical reactions reported in psychiatric patients. Employ usual precautions in treating anxiety states with evidence of impending depression; suicidal tendencies may be present and protective measures necessary. Variable effects on blood coagulation reported very rarely in patients receiving the drug and oral anticoagulants; causal relationship not established.

Adverse Reactions: No side effects or manifestations not seen with either compound alone reported with Librax. When chlordiazepoxide HCl is used alone, drowsiness, ataxia, confusion may occur, especially in elderly and debilitated; avoidable in most cases by proper dosage adjustment, but also occasionally observed at lower dosage ranges. Syncope reported in a few instances. Also encountered: isolated instances of skin eruptions, edema, minor menstrual irregularities, nausea and constipation, extrapyramidal symptoms, increased and decreased libido—all infrequent, generally controlled with dosage reduction; changes in EEG patterns may appear during and after treatment; blood dyscrasias (including agranulocytosis), jaundice, hepatic dysfunction reported occasionally with chlordiazepoxide HCl, making periodic blood counts and liver function tests advisable during protracted therapy. Adverse effects reported with Librax typical of anticholinergic agents, i.e., dryness of mouth, blurring of vision, urinary hesitancy, constipation. Constipation has occurred most often when Librax therapy is combined with other spasmolytics and/or low residue diets.



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P. 0186

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sign on the right
on your prescription.

When brain and bowel conflict...



It's time for the Peacemaker.

In irritable bowel syndrome* anxiety can aggravate intestinal symptoms, which may further intensify anxiety — a distressing cycle of brain/bowel conflict. Librax intervenes with two well-known compounds. The Librium® (chlordiazepoxide HCl/Roche) component safely relieves anxiety. And Quarzan® (clidinium bromide/Roche) provides antisecretory and antispasmodic action to relieve discomfort associated with intestinal hypermotility.

Dual action — for peace between brain and bowel. Because of possible CNS effects, caution patients about engaging in activities requiring complete mental alertness. Specify Adjunctive

LIBRAX®

Each capsule contains 5 mg chlordiazepoxide HCl
and 2.5 mg clidinium bromide

*Librax has been evaluated as possibly effective as adjunctive therapy in the treatment of peptic ulcer and the irritable bowel syndrome.
Copyright © 1987 by Roche Products Inc. All rights reserved. Please see summary of prescribing information on adjacent page.

State Licensure Under Fire

Kenneth C. Yohn, M.D.

Two bills introduced in Congress last September would impose federal standards on state medical licensing authorities. Dangerous enough in itself, such a precedent could lead to federal licensure. The Alabama delegation to the AMA House of Delegates introduced a resolution in the House calling for AMA opposition. Despite spirited dissent from Delegates representing Foreign Medical Graduate contingents, the Alabama position carried the day and was as adopted by the House. Following is the prepared text of the address by Alternate Delegate Kenneth C. Yohn, M.D., in support of the resolution before the Reference Committee. Although time constraints forced a shortening of the address, it represents the MASA position, which prevailed. Texts of the bills in question follow Dr. Yohn's commentary. — Ed.

Alabama physicians appeal to physicians from all states to support us in our resolution calling for vigorous AMA opposition to at least two bills before Congress.

If enacted, these bills would immediately dilute and ultimately destroy state authority over medical licensure. Their passage would be the entering wedge, the camel's nose under the tent, propelling this country toward federal licensure of the American physician.

The so called Fair Physician Licensure Reciprocity Standards Act of 1987, introduced by Democratic Congressman Stephen Solarz of New York, would amend title XIX (Medicaid) of the Social Security Act to prohibit a state (I am quoting the bill) "as a condition of Medicaid funding, from discriminating among licensed physicians in its medical reciprocity standards on the basis of the location of the medical school from which they graduated."

Democratic Congressman Jim Bates of California has introduced a similar bill, which goes on to specify areas in which equal treatment of FMGs shall be required by federal law.

Let me say at the outset that nothing that is to follow is intended to impugn the probity of these two Congressmen. Doubtless they feel they are serving the interests of some of their constituents. But our constit-

continued on page 27

Before prescribing, see complete prescribing information in SK&F LAB CO. literature or PDR. The following is a brief summary.

Contraindications: There are no known contraindications to the use of 'Tagamet'.

Precautions: While a weak antiandrogenic effect has been demonstrated in animals, 'Tagamet' has been shown to have no effect on spermatogenesis, sperm count, motility, morphology or in vitro fertilizing capacity in humans.

In a 24-month toxicity study in rats at dose levels approximately 9 to 56 times the recommended human dose, benign Leydig cell tumors were seen. These were common in both the treated and control groups, and the incidence became significantly higher only in the aged rats receiving 'Tagamet'.

Rare instances of cardiac arrhythmias and hypotension have been reported following the rapid administration of 'Tagamet' HCl (brand of cimetidine hydrochloride) injection by intravenous bolus.

Symptomatic response to 'Tagamet' therapy does not preclude the presence of a gastric malignancy. There have been rare reports of transient healing of gastric ulcers despite subsequently documented malignancy.

Reversible confusional states have been reported on occasion, predominantly in severely ill patients.

'Tagamet' has been reported to reduce the hepatic metabolism of warfarin-type anticoagulants, phenytoin, propranolol, chlordiazepoxide, diazepam, lidocaine, theophylline and metronidazole. Clinically significant effects have been reported with the warfarin anticoagulants; therefore, close monitoring of prothrombin time is recommended, and adjustment of the anticoagulant dose may be necessary when 'Tagamet' is administered concomitantly. Interaction with phenytoin, lidocaine and theophylline has also been reported to produce adverse clinical effects.

However, a crossover study in healthy subjects receiving either 'Tagamet' 300 mg. q.i.d. or 800 mg. h.s. concomitantly with a 300 mg. b.i.d. dosage of theophylline (Theo-Dur®, Key Pharmaceuticals, Inc.),

demonstrated less alteration in steady-state theophylline peak serum levels with the 800 mg. h.s. regimen, particularly in subjects aged 54 years and older. Data beyond ten days are not available. [Note: All patients receiving theophylline should be monitored appropriately, regardless of concomitant drug therapy.]

Lack of experience to date precludes recommending 'Tagamet' for use in pregnant patients, women of childbearing potential, nursing mothers or children under 16 unless anticipated benefits outweigh potential risks; generally, nursing should not be undertaken in patients taking the drug since cimetidine is secreted in human milk.

Adverse Reactions: Diarrhea, dizziness, somnolence, headache, rash. Reversible arthralgia, myalgia and exacerbation of joint symptoms in patients with preexisting arthritis have been reported. Reversible confusional states [e.g., mental confusion, agitation, psychosis, depression, anxiety, hallucinations, disorientation], predominantly in severely ill patients, have been reported. Gynecomastia and reversible impotence in patients with pathological hypersecretory disorders receiving 'Tagamet', particularly in high doses, for at least 12 months, have been reported. Reversible alopecia has been reported very rarely. Decreased white blood cell counts in 'Tagamet'-treated patients (approximately 1 per 100,000 patients), including agranulocytosis (approximately 3 per million patients), have been reported, including a few reports of recurrence on rechallenge. Most of these reports were in patients who had serious concomitant illnesses and received drugs and/or treatment known to produce neutropenia. Thrombocytopenia (approximately 3 per million patients) and a few cases of aplastic anemia have also been reported. Increased serum transaminase and creatinine, as well as rare cases of fever, interstitial nephritis, urinary retention, pancreatitis and allergic reactions, including hypersensitivity vasculitis, have been reported. Reversible adverse hepatic effects, cholestatic or mixed cholestatic-hepatocellular in nature, have been reported rarely. Because of the predominance of cholestatic features, severe parenchymal injury is considered highly un-

likely. A single case of biopsy-proven periportal hepatic fibrosis in a patient receiving 'Tagamet' has been reported.

How Supplied: Tablets: 200 mg. tablets in bottles of 100; 300 mg. tablets in bottles of 100 and Single Unit Packages of 100 (intended for institutional use only); 400 mg. tablets in bottles of 60 and Single Unit Packages of 100 (intended for institutional use only), and 800 mg. Tiltab® tablets in bottles of 30 and Single Unit Packages of 100 (intended for institutional use only).

Liquids: 300 mg./5 ml., in 8 fl. oz. (237 ml.) amber glass bottles and in single-dose units (300 mg./5 ml.), in packages of 10 (intended for institutional use only).

Injection:

Vials: 300 mg./2 ml. in single-dose vials, in packages of 10 and 30, and in 8 ml. multiple-dose vials, in packages of 10 and 25.

Prefilled Syringes: 300 mg./2 ml. in single-dose prefilled disposable syringes.

Plastic Containers: 300 mg. in 50 ml. of 0.9% Sodium Chloride in single-dose plastic containers, in packages of 4 units. No preservative has been added.

ADD-Vantage® Vials: 300 mg./2 ml. in single-dose, ADD-Vantage® Vials, in packages of 25.

Exposure of the premixed product to excessive heat should be avoided. It is recommended the product be stored at controlled room temperature. Brief exposure up to 40°C does not adversely affect the premixed product.

'Tagamet' HCl (brand of cimetidine hydrochloride) injection premixed in single-dose plastic containers is manufactured for SK&F Lab Co. by Travenol Laboratories, Inc., Deerfield, IL 60015.

* ADD-Vantage® is a trademark of Abbott Laboratories.

BRS-TG-L73B

Date of issuance Apr. 1987

SK&F LAB CO.
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In peptic ulcer:

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Tagamet®
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First to Heal

You'll both feel good about it.

RESULTS

Motrin[®] 800 TABLETS mg ibuprofen



Extra strength
Convenience
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A Century
of Caring
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A better alternative for hypertensives who are going bananas...

Spare your patients the extra cost—
in calories, sodium and dollars.

Spare your patients the rigors of
dietary K⁺ supplementation.

DYAZIDE[®]

25 mg Hydrochlorothiazide/50 mg Triamterene/SKF

Effective antihypertensive^{*} therapy...without the bananas

DAW

'DYAZIDE' AS WRITTEN.

^{*} Not for initial therapy. See brief summary.

Before prescribing, see complete
prescribing information in
SK&F CO. literature or PDR.
The following is a brief summary.

* WARNING

This drug is not indicated for initial therapy of edema or hypertension. Edema or hypertension requires therapy titrated to the individual. If this combination represents the dosage so determined, its use may be more convenient in patient management. Treatment of hypertension and edema is not static, but must be reevaluated as conditions in each patient warrant.

Contraindications: Concomitant use with other potassium-sparing agents such as spironolactone or amiloride. Further use in anuria, progressive renal or hepatic dysfunction, hyperkalemia. Pre-existing elevated serum potassium. Hypersensitivity to either component or other sulfonamide-derived drugs.

Warnings: Do not use potassium supplements, dietary or otherwise, unless hypokalemia develops or dietary intake of potassium is markedly impaired. If supplementary potassium is needed, potassium tablets should not be used. Hyperkalemia can occur, and has been associated with cardiac irregularities. It is more likely in the severely ill, with urine volume less than one liter/day, the elderly and diabetics with suspected or confirmed renal insufficiency. Periodically, serum K⁺ levels should be determined. If hyperkalemia develops, substitute a thiazide alone, restrict K⁺ intake. Associated widened QRS complex or arrhythmia requires prompt additional therapy. Thiazides cross the placental barrier and appear in cord blood. Use in pregnancy requires weighing anticipated benefits against possible hazards, including fetal or neonatal jaundice, thrombocytopenia, other adverse reactions seen in adults. Thiazides appear and triamterene may appear in breast milk. If their use is essential, the patient should stop nursing. Adequate information on use in children is not available. Sensitivity reactions may occur in patients with or

without a history of allergy or bronchial asthma. Possible exacerbation or activation of systemic lupus erythematosus has been reported with thiazide diuretics.

Precautions: The bioavailability of the hydrochlorothiazide component of 'Dyazide' is about 50% of the bioavailability of the single entity. Theoretically, a patient transferred from the single entities of triamterene and hydrochlorothiazide may show an increase in blood pressure or fluid retention. Similarly, it is also possible that the lesser hydrochlorothiazide bioavailability could lead to increased serum potassium levels. However, extensive clinical experience with 'Dyazide' suggests that these conditions have not been commonly observed in clinical practice. Angiotensin-converting enzyme (ACE) inhibitors can elevate serum potassium; use with caution with 'Dyazide'. Do periodic serum electrolyte determinations (particularly important in patients vomiting excessively or receiving parenteral fluids, and during concurrent use with amphotericin B or corticosteroids or corticotropin [ACTH]). Periodic BUN and serum creatinine determinations should be made, especially in the elderly, diabetics or those with suspected or confirmed renal insufficiency. Cumulative effects of the drug may develop in patients with impaired renal function. Thiazides should be used with caution in patients with impaired hepatic function. They can precipitate coma in patients with severe liver disease. Observe regularly for possible blood dyscrasias, liver damage, other idiosyncratic reactions. Blood dyscrasias have been reported in patients receiving triamterene, and leukopenia, thrombocytopenia, agranulocytosis, and aplastic and hemolytic anemia have been reported with thiazides. Thiazides may cause manifestation of latent diabetes mellitus. The effects of oral anticoagulants may be decreased when used concurrently with hydrochlorothiazide; dosage adjustments may be necessary. Clinically insignificant reductions in arterial responsiveness to norepinephrine have been reported. Thiazides have also been shown to increase the paralyzing effect of nondepolarizing muscle relaxants such as tubocurarine. Triamterene is a weak folic acid antagonist. Do periodic blood studies in cirrhotics with splenomegaly. Antihypertensive effects may be enhanced in post-sympathectomy patients. Use cautiously in surgical patients. Triamterene has been found in renal stones in association with the other usual calculus components. Therefore, 'Dyazide' should be used with caution in patients with histories of stone formation. A few occurrences of acute renal failure have been reported in patients on 'Dyazide' when treated with indomethacin. Therefore, caution is advised in administering nonsteroidal anti-inflammatory agents with 'Dyazide'. The

following may occur: transient elevated BUN or creatinine or both, hyperglycemia and glycosuria (diabetic insulin requirements may be altered), hyperuricemia and gout, digitalis intoxication (in hypokalemia), decreasing alkali reserve with possible metabolic acidosis. 'Dyazide' interferes with fluorescent measurement of quinidine. Hypokalemia is uncommon with 'Dyazide', but should it develop, corrective measures should be taken such as potassium supplementation or increased dietary intake of potassium-rich foods. Corrective measures should be instituted cautiously and serum potassium levels determined. Discontinue corrective measures and 'Dyazide' should laboratory values reveal elevated serum potassium. Chloride deficit may occur as well as dilutional hyponatremia. Concurrent use with chlorpropamide may increase the risk of severe hyponatremia. Serum PBI levels may decrease without signs of thyroid disturbance. Calcium excretion is decreased by thiazides. 'Dyazide' should be withdrawn before conducting tests for parathyroid function. Thiazides may add to or potentiate the action of other antihypertensive drugs. Diuretics reduce renal clearance of lithium and increase the risk of lithium toxicity.

Adverse Reactions: Muscle cramps, weakness, dizziness, headache, dry mouth; anaphylaxis, rash, urticaria, photosensitivity, purpura, other dermatological conditions; nausea and vomiting, diarrhea, constipation, other gastrointestinal disturbances; postural hypotension (may be aggravated by alcohol, barbiturates, or narcotics). Necrotizing vasculitis, paresthesias, icterus, pancreatitis, xanthopsia and respiratory distress including pneumonitis and pulmonary edema, transient blurred vision, sialadenitis, and vertigo have occurred with thiazides alone. Triamterene has been found in renal stones in association with other usual calculus components. Rare incidents of acute interstitial nephritis have been reported. Impotence has been reported in a few patients on 'Dyazide', although a causal relationship has not been established.

Supplied: 'Dyazide' is supplied as a red and white capsule, in bottles of 1000 capsules; Single Unit Packages (unit-dose) of 100 (intended for institutional use only); in Patient-Pak[™] unit-of-use bottles of 100.

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Internal
Revenue
Service



State Licensure

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uents are the millions of American patients who could be victimized by this legislation.

Perhaps the sponsors had no such result in mind and would be incensed at my suggestion. But if there is one valid observation in American lawmaking in recent decades it is what someone has called "the law of unintended results." The results of this legislation could be catastrophic to the finest health care system in the world.

These bills says that if graduates of foreign medical schools are examined differently from graduates of accredited American schools, this is "discrimination."

"Discrimination," as used in the bills, is a loaded word. It means that whoever practices such additional inquiries as the law would proscribe is, ipso facto, guilty of xenophobia, economic protectionism, and possibly ethnic and religious prejudice too.

Nonsense. We say these bills are sailing under the false colors of international brotherhood, tolerance, sweet charity and the true spirit of the melting pot called America.

They were saying something similar 140 years ago when the American Medical Association was born, beginning the long, hard fight for professional standards, strict licensing supervision, and the world's highest demands on medical education.

I need scarcely remind this audience of the details of that arduous journey against what historians of the period called the "fierce laissez-faire commercialism" of the 19th Century. But a brief overview is instructive.

The AMA, like many of our state associations, had to fight hammer and tong against the populist spirit that sneered at the "medical trust" as elitist and praised the concept that in this land of the free anybody could practice any trade he chose. Medicine was seen as scarcely different from shoeing horses.

Our professional forebears were called elitists and snobs because they sought to introduce European-style medical education and professional standards to this country. They were ridiculed and reviled by demagogues and by montebanks with a vested interest in minimum standards or none.

The gains of the mid-19th Century were lost as the century came to a close. The Association of American Medical Colleges, founded in 1876, disbanded in disarray and despair seven years later. The AMA established a Council on Medical Education that in 1905 joined representatives of state licensing boards and the Association of American Colleges to create a model program for training and licensing.

In 1906 the Council began to publicize the poor scores of candidates from weak medical schools. Diploma mills were everywhere. Backing for the AMA

reform movement came from the Carnegie Foundation for the Advancement of Teaching, which in 1909 took over the AMA's survey of medical schools and appointed Dr. Abraham Flexner to lead the investigation.

The rest, as they say, is history. The Flexner Report of 1910 was a devastating indictment of the state of medical education in the United States and of general competence in the medical profession. So great was the public revulsion over that report that by 1928 only 74 regular medical schools remained of the 154 counted two decades earlier. That number continued to decline for the next five years.

Storefront "medical colleges" vanished by the score.

All of the physicians within the sound of my voice are products of those sweeping reforms beginning some 60 years ago. And *now* because we are guardians of this relatively new tradition of excellence, we are held up to the charge of discrimination because we are more searching in our licensure of graduates of foreign medical schools than we are of graduates of schools known to us and under the strict monitoring of the Liason Committee for Medical Education.

If this be elitism, I plead guilty. If the dedication of the state licensing boards to the heritage of post-Flexner is discrimination, it is discrimination of the kind America, at this critical hour, needs more of, not less.

On all sides nowadays we see politicians donning the hair shirt to proclaim their grief for the low estate of American industrial competitiveness in world markets. We hear all manner of gnashing of teeth over the decline of quality in the United States. We are told *ad nauseum* that the major reason for our alarming trade deficits is not so much price as quality. Nobody wants what we make, they say, because we don't make it as well as the label "Made in the U.S.A." once stood for.

I do not know the truth of these breast-beatings. But I do know that one exception is made by virtually every such prophet of doom and gloom: American medicine is the best in the world. They may add that it costs too much, but they grant that every nation envies and would like to emulate the quality of medical care in the United States.

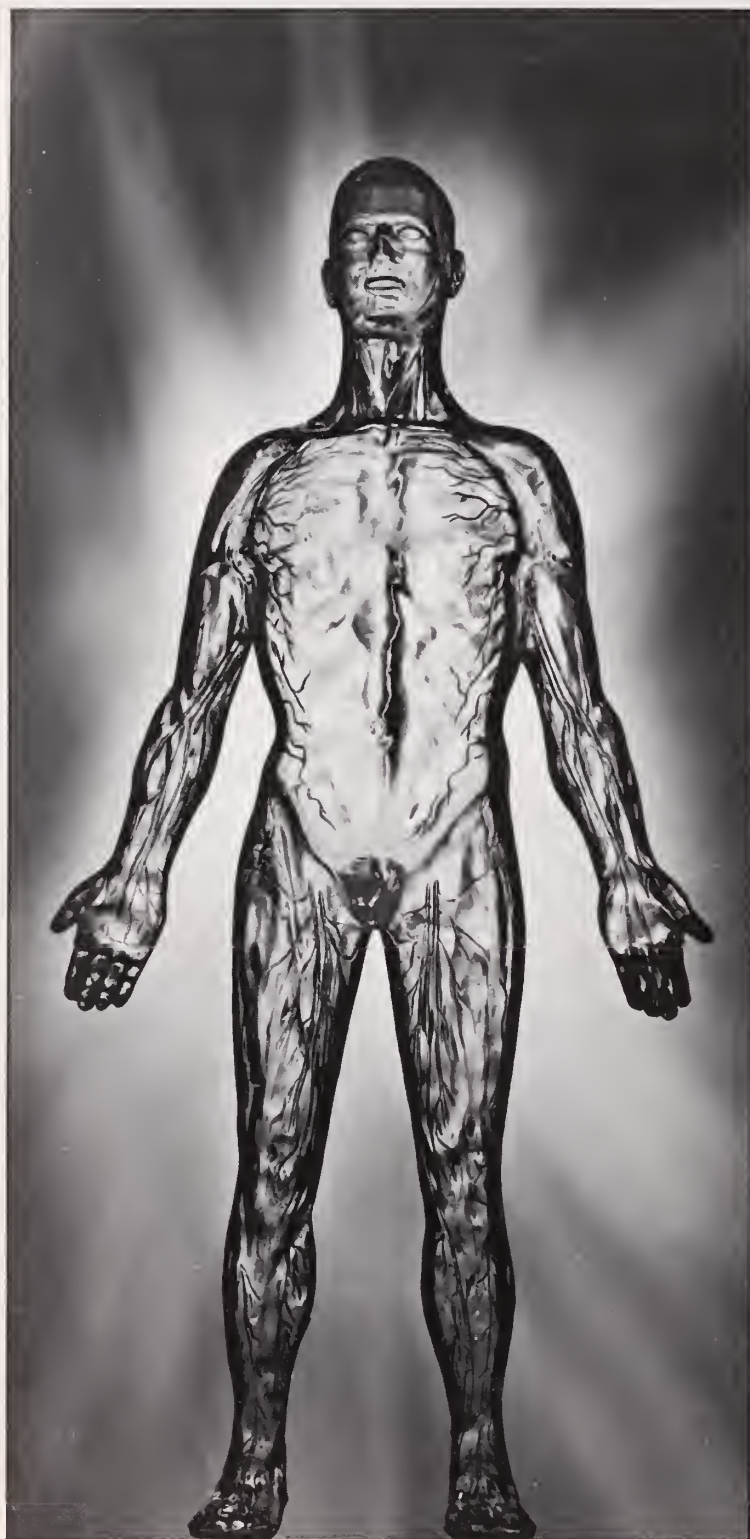
That didn't just happen. It came about because tens of thousands of American doctors made it happen by fighting state legislatures and public inertia to elevate the quality of medical education and the standards of medical practice in their states, assisted throughout by AMA.

Just as a jury of local citizens can best serve the ends of justice, so can a jury of local peers best judge who is to be trusted with the fragile art and science of medical practice.

If we are more searching in our examination of applicants from foreign medical schools it is because

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State Licensure

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we remember the bitter joke of populist "licensure" before AMA and Dr. Flexner showed the public how it was being victimized.

If we are charged with elitism in our sincere probing of the educational preparation of offshore medical graduates, let me paraphrase the famous words of a great American 23 years ago:

"I would remind you that extremism in the defense of our profession is no vice . . . that moderation in the pursuit of excellence is no virtue. . . ."

Please join us in urging the AMA's vigorous opposition to proposed legislation that would outlaw our efforts to insist on high standards of foreign medical education.

If we fail in this effort, of this you may be certain: as night follows day, other efforts will quickly follow to vest in the federal government virtually all medical licensure authority. That would open the floodgates in the name of egalitarianism and it would destroy American medicine.

100TH CONGRESS 1ST SESSION

H.R. 3241

To promote nondiscrimination in State medical licensure and medical reciprocity standards, and to amend title XIX of the Social Security Act.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 9, 1987

MR. BATES introduced the following bill; which was referred to the Committee on Energy and Commerce.

A BILL

To promote nondiscrimination in State medical licensure and medical reciprocity standards, and to amend title XIX of the Social Security Act.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SHORT TITLE

SECTION 1. This Act may be cited as the "Equal Opportunity for Medical Licensure and Reciprocity Act of 1987."

PURPOSE OF THE ACT

SEC. 2. The purpose of this Act is to provide that any person that is a medical school graduate of a medical school outside the United States shall be given equal access to practice medicine within any jurisdiction in the United States. Discrimination against any graduate of a medical school outside the United States shall not be tolerated in licensure, reciprocity, reimbursement, residency, medical staff academic appointments, and professional society membership. The De-

partment of Health and Human Services shall enforce the provisions of this law.

SEC. 3. Any person who is a practicing and licensed physician in the United States and who graduates from a medical school outside the United States shall not be denied equal access to practice medicine within any jurisdiction in the United States.

SEC. 4. For any person who is a practicing and licensed physician in the United States, no provision of law, regulation, policy, or requirements for obtaining or maintaining a license to practice medicine shall discriminate against a person who is a graduate of a medical school outside the United States because of such person's status as a graduate of such a medical school.

SEC. 5. Any person who is a medical graduate from a medical school outside of the United States and has completed the United States postgraduate training and obtained a license to practice medicine in any State of the United States shall not be subjected to any conditions or requirements which materially differ in any respect from such conditions or requirements as applied to graduates from medical schools within the United States in relation to the following:

(a) any examination required as a condition to practice medicine or to continue the practice of medicine in the United States;

(b) any requirements or qualification criteria necessary to obtain or maintain medical board certification in the United States;

(c) access to residency training positions at any medical school, hospital or other medical facility within the United States;

(d) access to any form of financial assistance from the United States Government or any agency thereof to be provided to a medical graduate or to be provided to any person or entity where such financial assistance is in any way based on the status or origin of a medical graduate;

(e) State and jurisdictional standards and evaluation criteria for determining the method or manner of granting reciprocity to any medical graduate to practice medicine in such State or jurisdiction;

(f) membership in any public medical association or organization;

(g) any other such circumstances concerning the licensing of medical providers and/or the professional requirements within the medical system of the United States;

(h) that no Federal law shall be construed to require or permit discrimination in the payment for health care services which are furnished (or ordered to be furnished) by or under the supervision of a physician, solely on the basis that individual's qualification as a physician is based on the graduation from a medical school located outside the United States; and

(1) no retroactive laws or regulations shall be applied to any practicing and licensed physician of the United States who is a graduate of a medical school located outside the United States.

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State Licensure

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SEC. 6. The above provisions shall be equally applicable to conditions and requirements relating to any medical speciality as well as the general practice of medicine.

SEC. 7. The Secretary of Health and Human Services may not make a grant, loan guarantee, or interest subsidy under any provision of law to, or for the benefit of any school of medicine, unless the application for the grant, loan guarantee, or interest subsidy payment contains assurances satisfactory to the Secretary of Health and Human Services that the school of medicine will not discriminate in any way against any physician that is not a graduate of a medical school located within the United States.

SEC. 8. In order for any State to be eligible to receive payments pursuant to title XIX of the Social Security Act with respect to any calendar quarter which begins within one year after the date of enactment of this Act, a State shall adopt medical licensure and medical reciprocity standards which provide equal opportunity to any person who is a graduate of a medical school which is within the United States, and to any person who is a graduate of a medical school outside the United States and such person has completed the United States post-graduate training and obtained a license to practice medicine in any State of the United States.

SEC. 9. The Secretary of Health and Human Services shall develop regulations to carry out the provisions of this Act.

100TH CONGRESS 1ST SESSION

H.R. 3273

To amend title XIX of the Social Security Act to prohibit States, as a condition of medicaid funding, from discriminating among licensed physicians in its medical reciprocity standards on the basis of the location of the medical school from which they graduated.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 15, 1987

MR. SOLARZ introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend title XIX of the Social Security Act to prohibit States, as a condition of medicaid funding, from discriminating among licensed physicians in its medical reciprocity standards on the basis of the location of the medical school from which they graduated.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION I. SHORT TITLE.

This Act may be cited as the "Fair Physician Licensure Reciprocity Standards Act of 1987."

SEC. 2. CONDITION FOR MEDICAID FUNDING.

(a) IN GENERAL. — Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)) is amended —

(1) by striking "and" at the end of paragraph (48),

(2) by striking the period at the end of paragraph (49) and inserting "; and", and

(3) by inserting after paragraph (49) the following new paragraph:

"(50) provide that the State, in its medical reciprocity standards for physician licensure for individuals who have successfully passed a licensure examination (and are duly licensed) as a physician in one of the 50 States, the District of Columbia, the Virgin Islands, or Guam, does not distinguish among such individuals based on the location of the medical school from which the individuals graduated."

(b) EFFECTIVE DATE. — (1) The amendment made by subsection (a)(3) applies (except as provided under paragraph (2)) to payments under title XIX of the Social Security Act for calendar quarters beginning on or after the first day of the first calendar quarter that begins more than 1 year, without regard to whether or not final regulations to carry out such amendment have been promulgated by such date.

(2) In the case of a State plan for medical assistance under title XIX of the Social Security Act which the Secretary of Health and Human Services determines requires State legislation (other than legislation appropriating funds) in order for the plan to meet the additional requirement imposed by the amendment made by subsection (a)(3), the State plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet this additional requirement before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of the enactment of this Act. ◻

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Questioning the Physician's Broader Responsibilities[©]

Leif C. Beck, LL.B.*

Physicians are uniquely fortunate in one too-often overlooked way. Their professional activity serves the uniformly desirable purpose of helping people. Regardless of what motivating factors led them to choose medicine as a career, their work deals with medical conditions so people can lead healthier, more wholesome and satisfying lives.

Few other professionals can so directly bask in that fact. Attorneys (of which I am one), accountants and advertising agents, for instance, have a more tenuous relation to a uniform socially desirable purpose. Other health professionals play a less pivotal role in the same goal as physicians have. Perhaps only ministers, rabbis and priests can so directly equate their work with the highest goals espoused by our society.

Spiritual Question

Given the special opportunity to serve, though, to what extent do physicians actually seek to serve medicine's basic purposes? In my newsletter, *The Physician's Advisory*, I recently addressed this question under the provocative title: "Are You Doing Enough to Satisfy Your God?"

It put the question in spiritual terms, for all of us must ultimately answer such concerns. But it challenges you to consider your work patterns — and your underlying personal attitudes — as it relates to the community of man as well as to God.

So much good is done by each doctor. The orthopedist repairs his patient's broken bone or, through the wonder of arthroscopy, his torn ligament.

The family physician detects her patient's colonic polyps early enough to spare a 45-year old parent's life from cancer, and the pediatrician handles that parent's children's health problems — big and small — so these kids become healthy adults.

The anesthesiologist manages her cases so well that hundreds of in-hospital and ambulatory surgery cases give people years — and decades — of further productive life.

And so on for each physician in each specialty and practice setting.

Of course, physicians are for the most part extremely well paid for their work. They are at the top of the income scale, despite their long hours and the burdens upon them. Even though younger doctors worry whether medical practice will be as economically rewarding as in the past, especially in view of medical school debts, they are virtually certain to do at least reasonably well financially.

* The author is Chairman of the Health Care Group, Meetinghouse Business Center, 140 W. Germantown Pike, Suite 200, Plymouth Meeting, PA 19462 — (215) 828-1729, a medical management consultant and attorney advisor to physicians. This article was published in *Pennsylvania Medicine*, December 1987.

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Physician's Responsibilities

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The "Typical" Physician

As a medical management consultant and advisor to thousands of physicians over some 17 years now, I have developed a fairly good picture of how doctors think and act. There is admittedly enough variation from person-to-person that many people fall outside any generalizations. Nonetheless, some patterns are so strong that they deserve description.

The "typical," successful private practice physician — an admitted misnomer — works 10, 12 or more hours per day and assumes care of so many patients that his (and increasingly, her) day is hectic from start to finish. His or her commitment to each patient's best care is driven by a combination of an engrained professional ethic, or business need to provide good service and a fear of malpractice complications. Each patient served, indeed each procedure performed, represents an income flow on a piece-work basis; a procedure compensated at less than or no regular fee is considered "lost income."

Within this picture, many doctors accept Medicaid patients but a great many others refuse those cases. In my experience, however, "successful" doctors generally accept welfare patients only grudgingly. There is a haughtiness in the attitude that the Medicaid or freebie patient represents someone who receives something for nothing and then may turn around and bring a malpractice suit if the result is less than perfect.

Virtually all physicians have a general policy to reduce or write off the fee of any patient who has presented but truly cannot pay it, although that sort of patient is — if not referred on to the "clinic" — hardly sought with any real enthusiasm.

This psyche may be understandable. There is so much to do for patients who, directly and through their insurers, will pay for each separately itemized procedure that helping someone for free is virtually anathema. (One high-income physician wrote me in protest that he "gives away over \$100,000 per year," presumably counting Medicare and Medicaid disallowances as well as write-offs, and challenged whether non-physicians are so generous.)

No Soft Answers

Whether or not you perfectly fit the above-described picture, the difficult question is if those practice patterns are satisfactory within your greater spiritual and human obligations. Is it "enough" to provide your wonderful services through your system geared primarily to those patients who can pay — or whose insurers can pay — your fees?

Are God and humanity sufficiently served when you offer your good works only within your own practice's pattern? And are your greatest obligations satisfied when you practice good medicine, live a generally moral life and devote the rest of your attention to your family?

The teachings of virtually all our religions take us past our society's comfort zone and answer "no" to these questions. While not opposing wealth, for instance, the Bible — both Jewish and Christian — demand concern and effort for the poor. And it calls for that concern and effort to be genuine enough to withstand your — and your God's — critical evaluation.*

All of us tend to avoid that critical evaluation; we prevent logic from pursuing its natural course when it affects our built-in priorities. An affluent suburban church-goer may, for example, give some money and a bit of executive time — but not his actual on-site presence — to a charitable effort. And a physician may take pride in seeing poor patients for no or low fee if they somehow find their way to his/her office — but not affirmatively reach out and seek those people who really need his/her skills.

A number of teachings show how our society's systems are subtly but insidiously stacked against the poor.† You need not be a "bleeding heart liberal" — I am not — to see how poor people lack access to medical care and other basic needs which would be even minimally acceptable to our own families. Answering that the poor could find jobs and improve their own access to such care overlooks two basic flaws: the systems make this virtually impossible, and God demands concern for the less advantaged anyway.

Everyone's Question

Some doctors responded to these points by comparing their good works to those of non-physicians. "Who are you," one physician wrote me, "to chastize doctors when you probably don't do anything for the poor yourself?"

He made a good point. Every person — whether salesman, lawyer, corporate executive, medical management consultant, housewife or physician — faces the same questions. In response to that letter writer, I am heavily involved in an inner city, church-based

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* While the comments are in relation to the Christian and Jewish religions, it is believed that the same concerns are held in the world's other major religions. And even atheists should recognize society's needs as a matter of general personal morality.

† See, for instance, "Rich Christians in an Age of Hunger," by Ronald J. Sider. Inter-Varsity Press, Downers Grove, IL, 1984.

A WORD TO THE WHYS

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WHY AMA?

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WHY AMA?

The AMA can help you build and improve the efficiency of your practice through Practice Management seminars and audio visual courses. These programs are designed to assist you in every phase of your practice by providing you with practical information about business procedures and management techniques. Practice Management: it's one more good reason why you should be a part of the AMA.

To Join, Contact your county or state medical society or write:
Division of Membership, AMA, 535 North Dearborn Street, Chicago,
Illinois 60610 or call collect, (312) 751-6196.



Physician's Responsibilities

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health center's operations. Other non-physicians I know expend far greater efforts for "worthy projects" than do I. And many people are oblivious to the whole issue.

Some of us non-physicians are envious of doctors in this regard. Physicians have the privilege of being able to provide direct, "hands on" service to needy people; others' training allows them only to help organize, finance and, at best, manage the efforts. Would that we could operate on a blind woman so she can see again on a Project Hope third-world venture or help an impoverished Indian reservation improve its infant mortality rate.

The physician thus faces the same spiritual question that may puzzle non-doctors, but the physician has a special opportunity to answer it. The "good works" in private medical practice may be "enough" to satisfy his or her social and religious obligations — or they may be insufficient.

What to Do?

Some doctors have answered these concerns head-on. They committed themselves during their training to serve the poor, recognizing that health is a basic need which they can help provide in service to God. These mostly young doctors made this "total commitment" right after residency, accepting a reduced life style before they experienced their peers' affluence.

The Executive Director of the Christian Community Health Fellowship, located in Philadelphia, reports that the odds of someone's leaving normal practice patterns for a "total commitment" are virtually nil. A few doctors have, however, taken half-steps. In Denver, Colorado, a successful two-doctor suburban practice opened a second office in the inner city. One partner gives 60% of his time to the low-income site and 40% to the affluent office.

In Pennsylvania, two successful family practitioners are expressing their Mennonite faith three days a week in Philadelphia — 75 miles away from their homes

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The American Medical Association and your state and county medical societies believe in the value of teamwork — and the necessity of it, in the face of an increasingly complex professional environment.

We also believe that medical societies have certain tasks that the individual physician couldn't possibly assume — and shouldn't have to.

For example, to keep government regulations from interfering with your practice, we effectively represent your interests at local and national levels.

To influence policies of organized medicine with which you disagree, we provide the means to have your views heard and respected.

And to keep you up to date on the latest medical advances, we publish JAMA, AM News, specialty, state, and county journals.

In fact, for all the times you can't operate alone, your medical societies will be there. Working with you to defend your rights and protect your freedoms.

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For more information, contact your county or state medical societies, or call the AMA collect at 312/751-6196. Or return the coupon below to your state or county medical society.

- ☐ Please send me information on AMA, county, and state society membership.
☐ I am a member of my county and state societies; please send me information on joining the AMA.

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A black and white reproduction of Michelangelo's 'The Creation of Adam' is the background of the advertisement. It shows two hands reaching toward each other, with a small gap between the index finger of the hand on the right and the index finger of the hand on the left. The text 'Leave your mark on life.' is superimposed on the upper left portion of the image.

Leave your mark on life.

You don't have to move mountains to make a difference on this earth. Or be a Michelangelo to leave your mark on it.

Leaving even the smallest legacy to the American Cancer Society can help change the future for generations to come. By including the American Cancer Society in your will, you'll be leaving a loving and

lasting impression on life.

You see, cancer is beatable. The survival rate for all cancers is already approaching 50% in the United States.

You'll be giving a gift of life to the future. And giving life is the greatest way of leaving your mark on it.



For more information, call your local ACS Unit or write to the American Cancer Society, 4 West 35th Street, New York, NY 10001.

Physician's Responsibilities

continued from page 36

and practices. In an extremely underprivileged inner city area, they make house calls, broadly counsel patients and steer them to pastoral help as requested.

Other Approaches

Most of you may be unable to commit so heavily as these doctors. But there are still many opportunities.

One younger physician wrote in reply to my newsletter challenge. He is still building his specialty practice — barely breaking even — while saddled with debts. Though he feels he must jealously guard his “paying patient” time, he said this:

“However, I am going to try to institute a program through local churches and relief programs whereby my office can see one referred medically indigent patient per day in this coming year. Thus, this could be just under 300 people served at reduced rates or gratis. The tough question to answer is whether even that is enough.”

The wonderful thing about this young doctor is that he is going to actively seek out the needy patients. This is a significant difference from staying in one's regular work environment, with its physical and emotional comforts, providing whatever service to whom-ever comes along.

Perhaps you, too, might consider taking your skills to people who cannot otherwise find you or do not even know your help is available. Maybe the sense of greater obligation leads you to offer yourself in a role different from the all-consuming one you usually play.

Another physician wrote that he and several like-minded physician friends in their late 40s and early 50s are talking about putting together a medical venture for the poor. They would take themselves to the people, not sit back and wait for the people to find them.

The needs and your opportunities extend throughout the world. Though much can be done in America's ghettos, the abject disadvantages in India, Africa and parts of Central America are even more compelling. Contributing a few weeks or a sabbatical absence to such service agencies as Project Hope or the Luke Society can be extremely helpful. As one doctor who has participated in a number of them wrote:

“Those physicians who do voluntary community service, whether in their own locality or on an international basis, find that their satisfaction with their work and with life increases, their self-esteem increases; and those who involve their families in this work find that their family relationships are nurtured.”

Facing the Question

A minister said this about medical doctors:

“The knowledge they have and the talents given

them are things that they have been given by God. They owe much to Him and need to return much.”

Complaints about the medical profession's changed circumstances — including the malpractice climate, government regulation and big business' influence — fail to change this basic, underlying reality.

Just as everyone else, each physician should face the question. Is he or she doing “enough” to satisfy the spiritual concerns that, though generally submerged from critical thought, must present themselves occasionally during one's life? Physicians have the privilege — and the obligation — to answer it more directly and with greater potential satisfaction than other people.

What about you? Are you willing to ask if you are really conducting your life — and your medical talent — as your God would expect? And if you ask, how will you answer the question and act upon it? •

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At the very least you can, quite easily, find out more about how the Council works and what it does. Simply write to: Robert P. Keim, President, The Advertising Council, Inc., 825 Third Avenue, New York, New York 10022.



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A defense against cancer can be cooked up in your kitchen.

There is evidence that diet and cancer are related. Some foods may promote cancer, while others may protect you from it.

Foods related to lowering the risk of cancer of the larynx and esophagus all have high amounts of carotene, a form of Vitamin A which is in cantaloupes, peaches, broccoli, spinach, all dark green leafy vegetables, sweet potatoes, carrots, pumpkin, winter squash, and tomatoes, citrus fruits and brussels sprouts.

Foods that may help reduce the risk of gastrointestinal and respiratory tract cancer are cabbage, broccoli, brussels sprouts, kohlrabi, cauliflower.

Fruits, vegetables and whole-grain cereals such as oatmeal, bran and wheat may help lower the risk of colorectal cancer.

Foods high in fats, salt- or nitrite-cured foods such as ham, and fish and types of sausages smoked by traditional methods should be eaten in moderation.

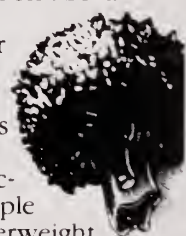
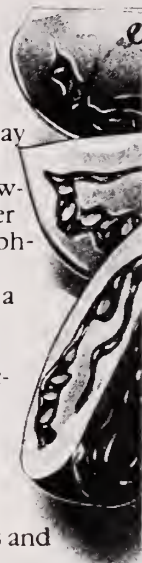
Be moderate in consumption of alcohol also.

A good rule of thumb is cut down on fat and don't be fat. Weight reduction may lower cancer risk. Our 12-year study of nearly a million Americans uncovered high cancer risks particularly among people 40% or more overweight.

Now, more than ever, we know you can cook up your own defense against cancer. So eat healthy and be healthy.

No one faces cancer alone.

 AMERICAN CANCER SOCIETY®



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“YES, THERE IS LIFE AFTER BREAST CANCER. AND THAT’S THE WHOLE POINT.”

—Ann Jillian



A lot of women are so afraid of breast cancer they don't want to hear about it.

And that's what frightens me.

Because those women won't practice breast self-examination regularly.

Those women, particularly those over 35, won't ask their doctor about a mammogram.

Yet that's what's required for breast cancer to be detected early. When the cure rate is 90%. And when there's a good chance it won't involve the loss of a breast.

But no matter what it involves, take it from someone who's been through it all.

Life is just too wonderful to give up on. And, as I found out, you don't have to give up on any of it. Not work, not play, not even romance.

Oh, there is one thing, though.

You do have to give up being afraid to take care of yourself.

 **AMERICAN CANCER SOCIETY®**
Get a checkup. Life is worth it.

AUXILIARY



*Mrs. Lamar Thomas
A-MASA President*

Aaron Lopez, M.D., 1800-1873

Dr. Aaron Lopez was one of the founders of the Medical Association of the State of Alabama in 1847 and was elected Vice-President of the American Medical Association in 1850.

He was the great, great grandfather of my husband, E. Lamar Thomas, Orthopedic Surgeon in Birmingham. The information in this article was compiled through family history, the archives at MSMA and a paper presented by the late Dr. Emmett B. Carmichael to the Alabama Academy of Science in 1965.

Dr. Lopez was born in 1800 in Charleston, South Carolina. He received his M.D. degree from the College of Physicians and Surgeons of Columbia University, New York City in 1822 returning to Charleston to practice. Around 1840 Dr. Lopez moved to Mobile where he became a highly respected member of the local practitioners.

When the Medical Association of the State of Alabama was organized December 1, 1847 in Mobile, Dr. Lopez was appointed chairman and served as president the following year.

The Association early interested itself in the establishment of an asylum for the insane of the State. Dr. Lopez, chairman of the Committee was delegated to memorialize the Legislature on the subject and reported in 1851 to the Association that the matter was likely to receive action in the General Assembly then in session. The hospital was authorized February 6, 1852.

Dr. Lopez also served on the following committees: a. Committee to Publish the Annual Transactions; b. Medical Education and c. Code of Medical Ethics.

He served as a delegate to the American Medical Association for several years. His many committee

reports and motions before the MSMA and the AMA serve to show that he not only had organization ability but that he knew how to express himself in a clear style.

It seems that Dr. Lopez suffered a stroke in the late 1860's and was forced to discontinue his practice, moving to Memphis to live with his son. He died in 1873.

The following excerpts are taken from the lengthy Annual Oration delivered by Dr. Lopez to the Medical Association meeting in 1854. He verbalized the concern of the Association to standardize medical credentials and to protect the public from unqualified practitioners:

"Fellows of the Association: The theme I have selected, in obedience to your call, is, *The mutual relations that should exist between the representatives of a commonwealth and its medical men.*

"I come, then, to join in bonds of holy wedlock the sciences of Medicine and Legislation. The People's safety is the highest law, . . . I seek to bring together the people and their lawgivers. . . . I desire to unite to the labors of medical men, devoted to the physical preservation of the State, the earnest and effective cooperation of the people's agents, in order that the State may reap the benefit of her subjects. . . .

"The progress of SCIENCE, and consequently of TRUTH, cannot fail to impress the reasoning man with the conviction, that degenerating influences are reflected upon the intellectual integrity of communities, accordingly as their physical organization improves or deteriorates. . . . Medical history . . . causes to show how necessary it has become to legislate by acts that 'grasp beyond a grain, and look beyond an hour.' . . .

"Ask yourselves, whether it be prudent or wise to adopt a policy that retards their advancement, discourages their efforts, and represses the spirit that should prompt them, rather than throw your buckler between them and sinister influences, deeply calculated to operate as fatally upon yourselves and your constituents, as upon a Profession whose object is exalted, and whose utility is unquestioned. . . .

"But figures and statistics verify my statements. They prove that in proportion as a provident legislation invests qualified persons with all things pertaining to sanitary and hygienic regulations . . . so far will it accomplish its highest duty, and so much will it enhance the obligation under which it lays its citizens. . . .

"It is time for men who aspire to guide the councils of a State, to aspire also to a knowledge of what is passing around them; to raise themselves upon the table land of discovery, and look around upon the groundwork and superstructures which Science has been erecting, and to see, amid the proudest and most honorable of its successful servants, the MEDICAL

PROFESSION, hand in hand with every virtue and every progress that can adorn and dignify the human character. . . .

"Associations spread themselves from the metropolis to the counties; laws ethical and educational usurp the place of wild and speculative empiricism. . . .

"The history of past years, both in this State and others, . . . point out the mode and measure of redress. . . . Respect and confidence will henceforth be commanded, not sought. The public eye must throw off the beam, and public judgment be aroused to a just appreciation of men engaged in their great work of MEDICAL REFORM. . . .

"The quack and the nostrum vender have no business within the same area with the man of science, for, like the fig-tree of the parable, 'he cumbereth the ground.' . . .

"We meet biennially under the vigilant eye of the State, in order, that its agents may learn to distinguish between the true and the false — that they may check the error of a mistaken policy — when their too liberal construction of equal rights would prompt them to legalize men, whom neither study, acquirements nor science can direct, and who really seek to tamper with the most vital interests of the State. . . .

"MEDICAL REFORM is passing its watchword across the broad waves of the Atlantic, and in every town and hamlet of our own country . . . whose only aim is to ennoble and instruct, and to raise the lives of our fellow beings beyond the reach of the common murderer. . . .

"The State may be willing . . . to conform to the call of duty, but she must likewise be permitted to exercise this high prerogative according to the lights before her. . . .

". . . no physician dare avow himself indifferent to the spirit that pervades his professional atmosphere. . . .

"To your keeping, then, my young brethren, we consign the future destiny of Alabama's medical character. Cherish and protect it in TRUTH, HONOR and FIDELITY." □

Carole

See the improvement in the first week¹

- Sleep improvement in 74% of patients after first h.s. dose²
- Significantly faster relief—62% of total four-week improvement evident in first week versus 44% with amitriptyline alone¹
- Dramatic first-week reduction in somatic complaints²

% Reduction in Somatic Symptoms²

Vomiting	Nausea	Headache	Anorexia	Constipation
Reduced 90%	Reduced 86%	Reduced 72%	Reduced 62%	Reduced 60%

- Only 1/3 the dropout rate due to side effects of amitriptyline alone, although the incidence of side effects is similar¹

Caution patients about the combined effects of Limbitrol with alcohol or other CNS depressants and about activities requiring complete mental alertness, such as operating machinery or driving a car. In general, limit dosage to the lowest effective amount in elderly patients.


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In moderate depression and anxiety

Limbitrol[®]

Each tablet contains 5 mg chlordiazepoxide and 12.5 mg amitriptyline (as the hydrochloride salt) 

Limbitrol DS[®]

Each tablet contains 10 mg chlordiazepoxide and 25 mg amitriptyline (as the hydrochloride salt) 

References: 1. Feighner JP, et al. *Psychopharmacology* 61: 217-225, Mar 22, 1979. 2. Data on file, Hoffmann-La Roche Inc., Nutley, NJ.

Limbitrol[®]

Tranquilizer—Antidepressant

Before prescribing, please consult complete product information, a summary of which follows:

Indications: Relief of moderate to severe depression associated with moderate to severe anxiety.
Contraindications: Known hypersensitivity to benzodiazepines or tricyclic antidepressants. Do not use with monoamine oxidase (MAO) inhibitors or within 14 days following discontinuation of MAO inhibitors. Severe hyperpyretic crises, severe convulsions and deaths have occurred with concomitant use, then initiate cautiously, gradually increasing dosage until optimal response is achieved. Contraindicated during acute recovery phase following myocardial infarction.

Warnings: Use with great care in patients with history of urinary retention or angle-closure glaucoma. Severe constipation may occur in patients taking tricyclic antidepressants and anticholinergic-type drugs. Closely supervise cardiovascular patients. (Arrhythmias, sinus tachycardia and prolongation of conduction time reported with use of tricyclic antidepressants, especially high doses. Myocardial infarction and stroke reported with use of this class of drugs.) Caution patients about possible combined effects with alcohol and other CNS depressants and against hazardous occupations requiring complete mental alertness (e.g., operating machinery, driving).

Usage in Pregnancy: Use of minor tranquilizers during the first trimester should almost always be avoided because of increased risk of congenital malformations as suggested in several studies. Consider possibility of pregnancy when instituting therapy; advise patients to discuss therapy if they intend to or do become pregnant.

Since physical and psychological dependence to chlordiazepoxide have been reported rarely, use caution in administering Limbitrol to addiction-prone individuals or those who might increase dosage, withdrawal symptoms following discontinuation at either component alone have been reported (nausea, headache and malaise for amitriptyline, symptoms [including convulsions] similar to those of barbiturate withdrawal for chlordiazepoxide).

Precautions: Use with caution in patients with a history of seizures, in hyperthyroid patients or those on thyroid medication, and in patients with impaired renal or hepatic function. Because of the possibility of suicide in depressed patients, do not permit easy access to large quantities in these patients. Periodic liver function tests and blood counts are recommended during prolonged treatment. Amitriptyline component may block action of guanethidine or similar antihypertensives. When tricyclic antidepressants are used concomitantly with cimetidine (Tagamet), clinically significant effects have been reported involving delayed elimination and increasing steady state concentrations of the tricyclic drugs. Concomitant use of Limbitrol with other psychotropic drugs has not been evaluated, sedative effects may be additive. Discontinue several days before surgery. Limit concomitant administration of ECT to essential treatment. See Warnings for precautions about pregnancy. Limbitrol should not be taken during the nursing period. Not recommended in children under 12. In the elderly and debilitated, limit to smallest effective dosage to preclude ataxia, oversedation, confusion or anticholinergic effects.

Adverse Reactions: Most frequently reported are those associated with either component alone: drowsiness, dry mouth, constipation, blurred vision, dizziness and bloating. Less frequently occurring

reactions include vivid dreams, impotence, tremor, confusion and nasal congestion. Many depressive symptoms including anorexia, fatigue, weakness, restlessness and lethargy have been reported as side effects of both Limbitrol and amitriptyline. Granulocytopenia, jaundice and hepatic dysfunction have been observed rarely.

The following list includes adverse reactions not reported with Limbitrol but requiring consideration because they have been reported with one or both components or closely related drugs.

Cardiovascular: Hypotension, hypertension, tachycardia, palpitations, myocardial infarction, arrhythmias, heart block, stroke.

Psychiatric: Euphoria, apprehension, poor concentration, delusions, hallucinations, hypomania and increased or decreased libido.

Neurologic: Incoordination, ataxia, numbness, tingling and paresthesias of the extremities, extrapyramidal symptoms, syncope, changes in EEG patterns.

Anticholinergic: Disturbance of accommodation, paralytic ileus, urinary retention, dilatation of urinary tract.

Allergic: Skin rash, urticaria, photosensitization, edema of face and tongue, pruritus.

Hematologic: Bone marrow depression including agranulocytosis, eosinophilia, purpura, thrombocytopenia.

Gastrointestinal: Nausea, epigastric distress, vomiting, anorexia, stomatitis, peculiar taste, diarrhea, black tongue.

Endocrine: Testicular swelling and gynecomastia in the male, breast enlargement, galactorrhea and minor menstrual irregularities in the female, elevation and lowering of blood sugar levels, and syndrome of inappropriate ADH (antidiuretic hormone) secretion.

Other: Headache, weight gain or loss, increased perspiration, urinary frequency, mydriasis, jaundice, alopecia, parotid swelling.

Overdosage: Immediately hospitalize patient suspected of having taken an overdose. Treatment is symptomatic and supportive. IV administration of 1 to 3 mg physostigmine salicylate has been reported to reverse the symptoms of amitriptyline poisoning. See complete product information for manifestation and treatment.

Dosage: Individualize according to symptom severity and patient response. Reduce to smallest effective dosage when satisfactory response is obtained. Larger portion of daily dose may be taken at bedtime. Single h.s. dose may suffice for some patients. Lower dosages are recommended for the elderly. Limbitrol DS (double strength) Tablets, initial dosage of three or four tablets daily in divided doses, increased up to six tablets or decreased to two tablets daily as required. Limbitrol Tablets, initial dosage of three or four tablets daily in divided doses, for patients who do not tolerate higher doses.

How Supplied: Double strength (DS) Tablets, white, film-coated, each containing 10 mg chlordiazepoxide and 25 mg amitriptyline (as the hydrochloride salt), and Tablets, blue, film-coated, each containing 5 mg chlordiazepoxide and 12.5 mg amitriptyline (as the hydrochloride salt). Available in bottles of 100 and 500, Tel-E-Dose[®] packages of 100, Prescription Paks of 50.

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Each tablet contains 5 mg clordiazepoxide and 12.5 mg amitriptyline (as the hydrochloride salt) ^(IV)

Limbitrol[®] DS

Each tablet contains 10 mg clordiazepoxide and 25 mg amitriptyline (as the hydrochloride salt) ^(IV)

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Please see summary of product information on adjacent page.

Alabama Medicine

March, 1988

Vol. 57, No. 9

JOURNAL OF THE MEDICAL ASSOCIATION OF THE STATE OF ALABAMA

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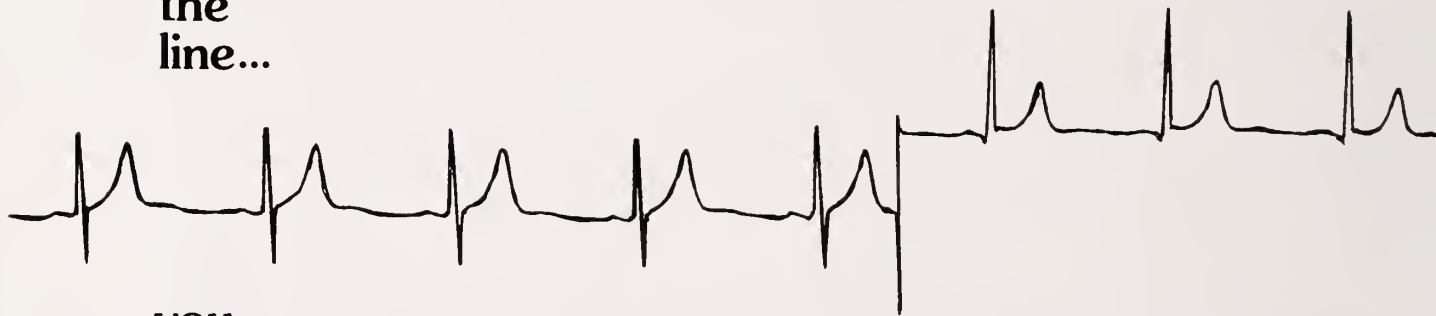
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Style: The first page should list title (please be brief), the author (or authors), degrees, and any institutional or other credits. Bibliographies must contain, in the order given: Name of author, title of article, name of periodicals with volume, page, month — day of month if weekly — and year. Number should be limited to absolute minimum. References should be numbered consecutively in order in which they appear in the text.

The Stylebook/Editorial Manual, published by the AMA, is the general reference for questions of style. It is particularly useful in the proper presentation of data. When conflicts occur between usage, etc., by an author and the stylebook, these will be resolved in favor of the author if his method is persuasive and logical.

Helpful to many writers is *The Elements of Style* by William Strunk, Jr., and E. B. White, which emphasizes brevity, vigor and clarity.

Final authority on grammar is Webster's *New International*, Unabridged, Second Edition.

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Table adapted from Facts and Comparisons (Nov.) 1984 and Catalano RB. The medical approach to management of pain caused by cancer. "Semin Oncol" 1975; 2; 379-92 and Reuler JB, et. al. The chronic pain syndrome: misconceptions and management. "Ann Intern Med" 1980; 93; 588-96.

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Drug Interactions: The CNS-depressant effects of VICODIN may be additive with that of other CNS depressants. When combined therapy is contemplated, the dose of one or both agents should be reduced. The use of MAO inhibitors or tricyclic antidepressants with hydrocodone preparations may increase the effect of either the antidepressant or hydrocodone. The concurrent use of anticholinergics with hydrocodone may produce paralytic ileus.

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Nursing Mothers: It is not known whether this drug is excreted in human milk; therefore, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS:

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Revised, April 1982.

5685

1. Hopkinson JH III: *Curr Ther Res* 24: 503-516, 1978
2. Beaver, WT *Arch Intern Med*, 141:293-300, 1981.

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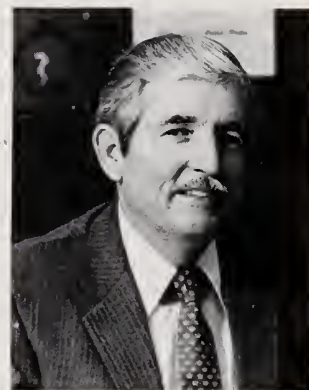
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S. Lon Conner
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EXECUTIVE DIRECTOR

F-15s and Medicare

A major reason the axe keeps falling on Medicare is that the price of an F-15 fighter is now \$39 million. It is said to be a fine state-of-the-art craft and I am sure its deployment enhances the security of the nation.

Just a couple of years ago, the price was about \$26 million. But nothing parallels the inflationary skyrocketing in military procurement. It's not ordinary hammers, toilet seats, and coffee pots costing hundreds of dollars that explain how we have spent something like \$1.6 trillion on defense in the last seven years — all of those are chicken feed. What runs up the bill are sophisticated weapon systems like the F-15.

Like most Americans, I want a powerful nation. Moreover, I have no real understanding of the relative merits of, say, 100 B-1 bombers compared with the dollar equivalent in MX missiles.

Although some scientists say that the Star Wars program is hopelessly visionary and diverts vast boodles of money that could be more effectively spent on conventional forces, I do not believe there are many of us competent to judge who is right.

So it is a debate that most of us simply cannot enter intelligently. I suspect there is an awful lot of waste and overcharging going on in defense spending, but I

don't know that. All I know is that the Department of Defense has increased its personnel strength these last few years to the point that it is now about the size of all other agencies of government combined. That's a lot of folks, many of them drawing large salaries for their indispensable technical acumen.

Additionally, just over the line in the private sector of the defense industry there are now some 3,000,000 civilian employees who are, for all practical purposes, working for the government too. They are the people who work directly with the Department of Defense on contracts, production schedules, quality control, costs, etc. Every weapons systems must include their salaries too in the mark-up. I would prefer not to know how many of them is included in the cost of one F-15.

The point is that we are now well along in a period of diverting money from butter to guns. Medicare is a butter item, a major one. It gets axed, but the defense contractors must be paid for the F-15. The health care profession, in all its roots and branches, is subject to constant, searching criticism of cost increases that are relatively trivial compared to those in the defense industry.

Weapon makers may occasionally be embarrassed when the General Accounting Office finds it charges

the Army \$800 for a hammer or the Navy \$1,200 for a toilet seat, but by and large it escapes the same kind of constant, scathing criticism that is systematically directed at physicians and hospitals. I think the explanation lies in the remoteness of weapons and their other-worldly mystery compared with the proximity of health care.

Few critics would be so bold as to say an F-15 should cost only \$30 million, for example, but those same critics have no hesitancy at all to charge that a surgical procedure costs twice as much as it should.

They know they can get by with that because most citizens have had some experience with medical costs in recent years, while they have had no occasion at all to compare the price, or relative merits, of an F-15 with an F-16. Most of us are quite willing to let military experts be the judge of weapons and their price tags. But that same forbearance is not transferred to medical care: everyone is an instant expert on the exorbitant costs of getting sick.

Many Americans well remember what last-week's critic of health care costs said but almost none of them can remember the warning of inflated military costs given to us by none other than the last General we had in the White House, Dwight D. Eisenhower.

When he left office, this career military man warned the country to beware of the "military-industrial complex." If anyone other than a military hero had said that, he would have been denounced as subversive. But here was one of the most beloved, astute and courageous military men in our history warning us of the excesses in the profession of arms. This same hero said even earlier, in 1956, that the nation must learn to strike a balance, as he put it, between "the minimum requirements in costly implements of war and the health of our economy."

In that little rumination Ike went on to give what can only be regarded as good advice to the President who takes office next January, whoever that might be:

"... Someday [Ike said in 1956] there is going to be a man sitting at my present chair who has not been raised in the military services and who will have little understanding of where slashes in their estimates can be made with little or no damage. If that should happen while we still have the state of tension that now exists, I shudder to think of what could happen to this country."

The next President, the pundits are saying, will be Hoover II. That is to say, he will preside over a towering deficit and a \$2 trillion debt that was simply unimaginable a few years ago. He will be met with demands from all sides to provide more wherewithal to health care, to education, to housing, to "rebuilding the infrastructure of the nation," more billions for the superconductor super-collider, more to the strategic defense initiative, more to the nation's space program, money to bail out agriculture again, strengthen the

banks — and so on, the list is endless. All this, of course, must be provided without new taxes, or only minimal ones.

As a people, we must decide what it is we must have and are willing to pay for. We can't have everything. By any estimate, austerity lies ahead. We can't have endless streams of F-15s rolling out of the factories unless we provide the means to pay for them. We can't have all the expensive technology of modern medicine unless we are willing to pay for it.

And we must make some choices that we have been avoiding at least since the Vietnam War — we must agree on Ike's reasonable balance between "costly implements of war and the health of our economy."

This country, once the greatest creditor nation on earth, is now the greatest debtor nation. We are in hock up to the dome of the nation's capitol.

We can no longer continue charging it to future generations. If the international markets have told us anything in the last year, it is that America's credit is being downgraded and our creditors are getting very, very antsy. With justification.

Every day we hear of various groups beating the drums for their favorite "national crisis." It will take billions, they say, to get the homeless off the streets but we must do it. Others say that for a few paltry tens of billions, we can answer some other pet need. Everyone has great ideas for expenditures. Almost nobody has any ideas about revenues.

I agree with Senator Hollins when he said at the time of the passage of the Gramm-Rudman-Hollins act "I want a lot of things for the country that people are demanding too. But I want to pay for them." People don't want to hear that.

We have simply reached a point in our national history when all the demands on limited resources must be decided on the basis of each one's priority when balanced against all the other demands. And the decision must be made, with national agreement, to pay \$X in more taxes for each item.

Just ahead are some bloody pitched battles over national priorities. Is saving the family farm, for example, more in the national interest than a new wing of F-15s? Not even Solomon himself would have wanted to adjudicate that one. □



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PRESIDENT'S PAGE



*Carl A. Grote, Jr., M.D.
President, MASA*

Riding the Whirlwind

One of the ways that you can tell that you are getting older is when you begin to sit around with other people your age and talk about the good old days.

I have not quite reached that time in life yet, but I do a lot of reminiscing and still wonder if the good old days were really good old days. Certainly, if I had to take everything that went on 30 years ago in place of what is going on today, I don't think I would want to make the trade. During my time in medicine there have been a lot of changes, but I would have to say that most of them have been good, though far from 100%.

Two of the biggest areas of change have been in the amount of medical care that is delivered and how that care is paid for. Thirty years ago there was a very close relationship between these two things; this relationship continues today. Just as a gas will expand to occupy whatever space is available to it, medical care will expand to consume all the dollars that are available to it. When I started out, medical care was relatively cheap, \$2 to \$4 for an office call, \$4 to \$5 for a house call, etc.

Most people did not have very much money. They paid for their medical care directly out of their own pockets. As a consequence, over all, people didn't receive a lot in the way of medical care. The rich

received more than the poor and there wasn't too much of a problem with overcrowding in hospitals. There were not enough people who could afford to fill them up.

As change came about, we could do more and more for people, certainly things that were unheard of 30 years ago. As these became available people began to demand more and more in the way of medical care. We in medicine were only too glad to provide it. Nowadays we would not dream of letting an injury go un-x-rayed. Who would have the courage to send a gentleman with chest pain home from the emergency room without at least doing an electrocardiogram? So as medical science has expanded so has the demand on the talents and skills of physicians as well as medical care facilities.

The other big change that took place in this time was in how medical care was paid for. In the 1950s a lot of patients paid for their medical care in cash. It was common to collect for most office visits in cash. And on the last day of hospitalization a patient frequently would ask how much he owed, reach into his left hip pocket and pay you right here on the spot.

Now most medical is paid for by a third party. This has somewhat changed the economic constraints on supply and demand in the field of medicine. When some-

one else is paying, the prevailing attitude is, "Let's take all we can get." Everyone was riding fat and happy for awhile on the crest of an economic boom in medicine. The patients couldn't get too much. They wanted the best of everything for themselves and for their families. We providers sure didn't care. We had never had it so good. Most of our bills were being paid and people were demanding more care all of the time.

After a few years it became apparent that this was a very expensive way of doing business. People began to talk about bringing about a change in the delivery of health care. They began to talk about more economical ways of delivering health care. So HMOs, PPOs, IPAs, etc., came into existence.

On the federal scene it became apparent that we needed to start paying for what we were getting. That is, in the past U.S. citizens had been paying only 75% for every dollar of health care delivered and then all of a sudden they decided that this had to stop. So regulation after regulation has been created both on the private sector and by the agencies of federal and state governments.

What has become apparent from all of these regulations though is that not only are they designed to make health care more cost effective but it has also the effect of rationing health care.

One thing that has become very very apparent from all of this is that the American people want the best of medical care. If we are sick, or if our loved ones are sick, or even someone we know well is sick — we want the best, don't spare anything.

The other thing that is readily apparent is that there is no limit to what medical science will be able to do in the future. The thing that has not been decided is how much medical care we are willing to pay for.

Many politicians, including our present President, have been ever too eager to advocate expanding medical benefits to the American people. However, none of them have been willing to see that the system is adequately financed. Though Mr. Reagan termed catastrophic health insurance the last full measure, I am sure the person who comes after him will find another measure someplace.

Now what is the point of all this? Certainly I have not told any of you anything that you did not already know. The point is that there have been changes during the last few years. Most of them have not been to the liking of most physicians in private practice.

These changes have not solved anything. What we have to look forward to is more changes in the future. And I don't think that they will be long in coming. There has never been a time when we needed to be together more. There has never been a time when medicine needed to speak in one voice. It is our only hope to have any input to what the future might bring.

One of the reasons organized medicine has been so

ineffective in the past is that often we get too busy fighting among ourselves and not supporting the organizations that would represent us. Then we get run over by some third party. How can the American Medical Association represent us if only 50% of the doctors belong? How can the Medical Association of the State of Alabama represent you if less than 20% attend the annual meetings or take any part in the policies and the positions of the Medical Association?

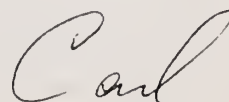
Almost two years ago HCFA authorized Harvard University to make a study and to come up with a relative value index. The American Medical Association asked to be a part and to have input into this study. This relative value index is due to be completed this summer. Some type of report should be considered in June at the annual meeting of the American Medical Association Meeting in Chicago.

Now, there is no way anyone is going to come up with the relative value index that is going to make everybody happy. So it is going to be hard for the delegates to that meeting in June to come away with any decisive action. I am afraid that what will happen is that we will end up with a big fight among ourselves and come away more divided than ever. So while we spend the next year or year and a half fighting among ourselves, HCFA will either adopt this relative value index or one of their own or some other method of payment and we will be left without any input at all.

Again, back to the point: The only way that doctors can have any input into the future changes that come about is to have strong organizations, both state and national. We must speak clearly and with one voice. We must be positive about what direction we want medicine to go not only for our benefit but for the benefit of our patients. We can't sit around and fuss about what is happening and what other people are doing to us and expect it to change. We can't stonewall it and hope to maintain the status quo and hope to prevail. (I think that non-participating physicians in Medicare have found this out.)

So saddle up, and get ready for a long, rough ride. But participate. Take part in your county medical society. Elect your delegates to the State Medical Association and see that they go and participate. Also, see that they represent you there and pass on to the leadership of the Medical Association your concerns and feelings.

Join the AMA and take an interest in what is going on and instruct your delegation as to what you want on the national scene. Things are bound to change, but we ought to have our say as they do. □



How Quickly Does Diet Make for Change? A Study of Body Mass Index (BMI)

Emanuel Cheraskin, M.D., D.M.D.
Professor Emeritus
University of Alabama Medical Center
in Birmingham

Abstract

Two hundred and forty-six presumably healthy young men (male dental students) were studied over a three-day period in terms of change in weight as measured by the Body Mass Index (BMI) following dietary alterations. The evidence convincingly shows that the only dietary changes which netted an alteration in body weight were the elimination of refined carbohydrate foods (producing a loss of weight) and an increase in refined carbohydrate foodstuffs (netting of weight gain).

Introduction

An earlier study¹ indicated that, under reasonably controlled conditions, one could significantly modify weight by changing refined carbohydrate intake. Specifically, the elimination of such foods netted an approximate 1.2 pounds loss within three days. Conversely, the addition of sucrose and glucose increased body weight 0.4 and 0.8 pounds respectively.

This report is designed to reexamine these same data in the light of one commonly-used height/weight ratios (BMI) in contrast to the earlier report which dealt with absolute weight.

Method of Investigation

Two hundred and forty-six presumably healthy junior dental students participated in this research/teaching program which extended over a six-year period. On Monday of a week, at approximately 10:00 A.M., each student underwent a general and oral examination, electrocardiography, a battery of biochemical, hematologic and urinary tests. Immediately after the examination, the sample was divided into a series of therapeutic subsets (Table 1).

In the first study, group 1 (40 subjects) was instructed to avoid, to the extent possible, all refined carbohydrate foods. The following year, group 2 was examined and subdivided into group 2a (n=22) and provided with a standard, over-the-counter multivitamin-trace mineral tablet on a daily basis; group 2b (n=22) was given an indistinguishable (lactose) placebo. The next year, group 3 was also divided into group 3a (n=22) provided with a 40-gram amino acid supplement; group 3b (n=22) an indistinguishable (methylcellulose) placebo. The following year, group 4 was divided into subsets with 4a (n=18) receiving a 40-gram tripe flour supplement while group 4b (n=19) was provided with an indistinguishable (methylcellulose) placebo. During the next academic year, group 5 was separated into 5a (n=23) given a 50-gram sucrose drink twice daily while 5b (n=16) received nothing. In the next school year, group 6a

(n=21) was provided with a 75-gram glucose drink thrice daily; the 21 subjects in group 6b were given an artificially sweetened drink indistinguishable from the glucose solution.

On Friday of the same week, each student underwent the same examination provided three days earlier by the same examiner with no knowledge of the earlier findings.

This unusual experimental design provided a singular opportunity to observe the clinical, physiologic, anthropometric, and biochemical effects of different diets in young and presumably healthy students during a three-day study.

This particular report deals exclusively with changes in weight as calculated from body mass index (weight expressed in kilograms divided by height squared in meters).

Results

Table summarizes the changes in body mass index with different therapeutic regimes. Listed are the eleven subsets, the body mass index initially and at the end of the experiment as well as the difference. Also included are the significance of the differences of the means² and the variances.³

Several points deserve special consideration. Firstly, it is clear from Table 2 that there are statistically significant differences in only three of the subsets and it is noteworthy that in all instances the dietary change consisted of refined carbohydrate foodstuffs. Specifically, the statistically significant differences are shown in groups 1, 5a, and 6a. Secondly, it is clear from Table 2 that, in only one instance, is there a statistically significant decline in weight. This is shown by a body mass index reduction of -0.170 which proved to be statistically significant ($t = 5.200$, $p < 0.001$). Thirdly, the only two other significant changes consisted of an increase in weight (groups 5a and 6a). Actually, in both instances, there was a statistically significant increase in weight as shown by differences of $+0.070$ ($t = 2.457$, $p < 0.05$) and $+0.104$ ($t = 3.048$, $p < 0.01$).

Discussion

It is noteworthy that the overall greatest change in body mass index was demonstrated in the category (group 1) characterized by the elimination of refined carbohydrate foods. It is noteworthy also that the group provided with the lesser refined carbohydrate supplement show the lesser increase in body weight. Specifically this will be noted by $+0.070$ and $+0.104$ in groups 5a and 6a respectively.

Additionally, the evidence is clear that the observations in this experiment with body mass index follow precisely early reports with changes in absolute weight¹ and the ponderal index.⁴

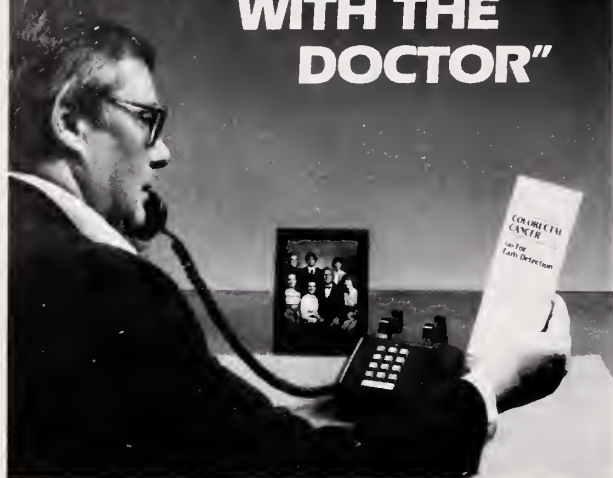
Summary and Conclusions

The information derived in this report from a study of body mass index (BMI) confirms the observations earlier in studies with absolute weight and ponderal index (PI). Specifically, in young and presumably healthy (and ostensibly not overweight) dental students, the elimination of refined carbohydrate foods nets a statistically significant reduction in absolute weight, in body mass index (BMI) and in ponderal index (PI). Conversely, the addition of refined carbohydrate foodstuffs under carefully controlled conditions nets an increased in body mass index (BMI) and absolute weight and a decrease in ponderal index (PI). ■

References

1. Cheraskin, E. How quickly does diet make for change? A study of weight (submitted for publication).
2. Walpole, R., Myers, R. Probability and Statistics for Engineers and Scientists, Third Edition. Macmillan Publishing Company, 269-296, 1985.
3. Walpole R. Introduction to Statistics, Second Edition. Macmillan Publishing Company, 205, 1974.
4. Cheraskin E. How quickly does diet make for change? A study of the ponderal index (submitted for publication).

"I'D LIKE TO MAKE AN APPOINTMENT WITH THE DOCTOR"



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We're here to help. You can reach us at your local American Cancer Society office or write to our Professional Education Department at National Headquarters, 90 Park Avenue, New York, N.Y. 10016. Ask about the Society's Colorectal Check program of professional and public education for the early detection of colorectal cancer.



*"Cancer of the Colon and Rectum: Summary of Public Attitude Survey," *Ca* 33:359-365, 1983 (Nov.-Dec.).



BRIEF SUMMARY

CONTRAINDICATIONS

There are no known contraindications to the use of sucralfate.

PRECAUTIONS

Duodenal ulcer is a chronic, recurrent disease. While short-term treatment with sucralfate can result in complete healing of the ulcer, a successful course of treatment with sucralfate should not be expected to alter the post-healing frequency or severity of duodenal ulceration.

Drug Interactions: Animal studies have shown that the simultaneous administration of CARAFATE with tetracycline, phenytoin, or cimetidine will result in a statistically significant reduction in the bioavailability of these agents. This interaction appears to be nonsystemic in origin, presumably resulting from these agents being bound by CARAFATE in the gastrointestinal tract. The bioavailability of these agents may be restored simply by separating the administration of these agents from that of CARAFATE by two hours. The clinical significance of these animal studies is yet to be defined.

Carcinogenesis, Mutagenesis, Impairment of Fertility: No evidence of drug-related tumorigenicity was found in chronic oral toxicity studies of 24 months' duration conducted in mice and rats at doses up to 1 gm/kg (12 times the human dose). A reproduction study in rats at doses up to 38 times the human dose did not reveal any indication of fertility impairment. Mutagenicity studies have not been conducted.

Pregnancy: Pregnancy Category B. Teratogenicity studies have been performed in mice, rats, and rabbits at doses up to 50 times the human dose and have revealed no evidence of harm to the fetus due to sucralfate. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when sucralfate is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Adverse reactions to sucralfate in clinical trials were minor and only rarely led to discontinuation of the drug. In studies involving over 2,500 patients, adverse effects were reported in 121 (4.7%). Constipation was the most frequent complaint (2.2%). Other adverse effects, reported in no more than one of every 350 patients, were diarrhea, nausea, gastric discomfort, indigestion, dry mouth, rash, pruritus, back pain, dizziness, sleepiness, and vertigo.

DOSAGE AND ADMINISTRATION

The recommended adult oral dosage for duodenal ulcer is 1 gm four times a day on an empty stomach.

Antacids may be prescribed as needed for relief of pain but should not be taken within one-half hour before or after sucralfate.

While healing with sucralfate may occur during the first week or two, treatment should be continued for 4 to 8 weeks unless healing has been demonstrated by x-ray or endoscopic examination.

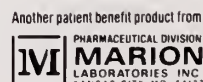
HOW SUPPLIED

CARAFATE (sucralfate) 1-gm pink tablets are supplied in bottles of 100 and in Unit Dose Identification Paks of 100. The tablets are embossed with MARION/1712.

Issued 3/84

References:

1. Grossman MI. *Scand J Gastroenterol* 58 (suppl 15):7-16, 1980.
2. Marks IN, in Hellemans J, Vantrappen G (eds): *Gastrointestinal Tract Disorders in the Elderly*. Edinburgh, Churchill Livingstone, 70-81, 1984.
3. Krentz K, Jablonowski H, in Hellemans J, Vantrappen G (eds): *Gastrointestinal Tract Disorders in the Elderly*. Edinburgh, Churchill Livingstone, 62-69, 1984.



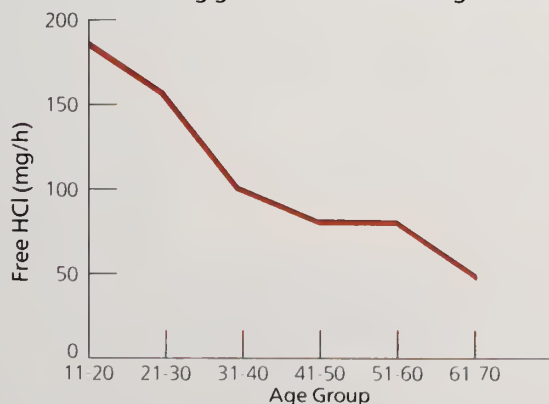
Specialized ulcer therapy

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If your duodenal ulcer patient is over 55, decreased mucosal resistance is more likely to cause an ulcer than hypersecretion of acid-pepsin.¹ A tendency toward lower acid secretion with advancing age has been shown.^{2,3}

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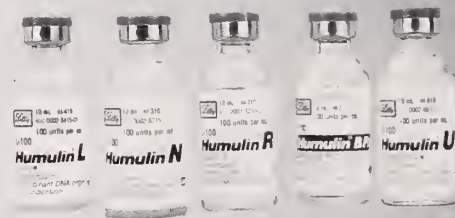
The clinical significance of insulin antibodies in the complications of diabetes is uncertain at this time. However, high antibody titers have been shown to decrease the small amounts of endogenous insulin secretion some insulin users still have. The lower immunogenicity of Humulin has been shown to result in lower insulin antibody titers; thus, Humulin may help to prolong endogenous insulin production in some patients.

Any change of insulin should be made cautiously and only under medical supervision. Changes in refinement, purity, strength, brand (manufacturer), type (regular, NPH, Lente®, etc), species/source (beef, pork, beef-pork, or human), and/or method of manufacture (recombinant DNA versus animal-source insulin) may result in the need for a change in dosage.

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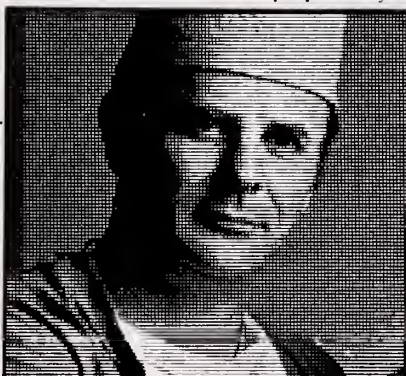
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Excessive Weight Gain and Pregnancy Outcome

William J. Crump, M.D.*

Abstract

Excessive prenatal weight gain has been associated with adverse perinatal outcome when studied in urban referral center populations. This study reports the outcome of 148 pregnancies showing weight gain exceeding 35 pounds in a population managed in a network of small community hospitals. When compared to those pregnancies of normal weight gain, primiparas had an increased frequency of hypertension, macrosomia, and primary cesarean section, and multiparas showed an increase in labor augmentation. Previously reported complications of diabetes, labor abnormalities, and assisted deliveries were not found to be increased in this relatively unselected population.

Twenty years ago, it was common to have physicians recommend dietary restriction during pregnancy.¹ Since that time, it has become apparent that higher pregnancy weight gain is associated with lower

likelihood of a low birth weight (LBW) infant.² In an effort to avoid the risk of neonatal morbidity and mortality associated with LBW delivery, physicians have subsequently advised liberal caloric intake. The result has been that in some populations, the average weight gain is now 33 pounds.³

Recent evidence has focused on the clearly obese patient who weighs more than 200 lb before or during pregnancy. These women have an increase risk of gestational diabetes⁴ and both acute toxemia and chronic hypertension.^{5,6} There is controversy over whether obesity alone is associated with an increased incidence of labor abnormalities,⁷ but if the infant is over 4000g, this risk is clear.⁸ Maternal obesity is an recognized risk factor for macrosomia, and these infants are subject to shoulder dystocia and birth trauma.⁹ The infant of an obese mother may also show hypoglycemia in the first few hours of life, although this is usually asymptomatic.¹⁰

Studies have also emphasized the prepregnant weight as an important determinant of pregnancy outcome. Optimal weight gain for the woman with normal prepregnant weight is around 20 pounds, and the overweight woman has the best outcome at a 16 pound weight gain. While the underweight woman is advised to gain 30 pounds, there is a definite increase in perinatal mortality rate with weight gain of more than 32

*Associate Professor of Family Medicine, University of Alabama in Huntsville, School of Primary Medical Care, 201 Governor's Drive, Huntsville, Alabama 35801.

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Excessive Weight Gain

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pounds, regardless of the prepregnant weight.¹¹ If a woman gains more than 35% of her prepregnant weight, there is an increased incidence of hypertension and a higher rate of oxytocin use, assisted delivery, and cesarean section. In multiparas, there is also a longer second stage.³

These previous studies included highly selected patient populations, often seen in an urban referral center. Whether the conclusions of these types of studies can be generalized to patients cared for in small community hospitals has been questioned recently.^{12, 13, 14} The purpose of this study was to compare the outcome of pregnancies with more than a 35 pound weight gain with those of normal weight gain, in a population managed in a network of small community hospitals.

Methods

The data were collected as part of the data base of the Alabama Perinatal Outcome Project (APOP). This network included seven sites, with a mean of 65 beds per hospital, with an average of 214 deliveries per year. No site had a staff neonatologist and one had a staff obstetrician. All fourteen participating physicians were family physicians, and all personally performed cesarean sections when required. Careful completeness, reliability, and validity measures were applied to each site. The network is representation of small hospital obstetrical care statewide, and complete methodology has been described previously.¹⁵

All deliveries attended by the participants during 1985 and 1986 were included in the data base. At the time of delivery, the attending physician designated the gestational weight gain as <20 pounds, 20-35 pounds, or >35 pounds. No data on prepregnancy weight was obtained. All other data base elements were provided on the same data collection form. All patients received continuous electronic fetal monitoring, and all other management decisions were left to the discretion of the attending physician. Labor abnormalities were classified as described by Freidman,¹⁶ and assisted delivery included forceps or vacuum extraction for any indication. FHR abnormality included recurrent variable or late decelerations, baseline tachycardia (>160 BPM) or bradycardia (<120), poor beat-to-beat variability, or any prolonged deceleration greater than two minutes duration. Fetal scalp pH determinations were not routinely performed in any participating hospital.

Hypertension was classified as toxemia, chronic hypertension, or toxemia super-imposed on chronic hypertension. Diabetes included all classes of glucose intolerance, and 75% of participants included a glucose screen as part of their routine prenatal care. Categorical variables were compared using the Chi-square methods, and means were assessed with the T-tests.

TABLE 1
Population Description

	(N = 750) 20-35 lbs NO (%)	(N = 148) >35 lbs NO (%)	p
Primipara	341(45.5)	87(58.8)	<.01
Diabetes	4(0.5)	2(1.4)	NS
Post dates	48(6.4)	16(10.8)	.08
Hypertension	48(6.4)	25(16.9)	<.001
Occiput Posterior	80(10.7)	20(13.5)	NS
Gestational Age (Wks)	Mean + SD 39.9 + 1.5	Mean + SD 40.2 + 1.3	NS

TABLE 2
Labor Variables

	(N = 750) 20-35 lbs NO (%)	(N = 148) >35 lbs NO (%)	p
Amniotomy	405(54.0)	74(50.0)	NS
Induction	57(7.6)	15(10.1)	NS
Augmentation	72(9.6)	25(16.9)	<.05
Abnormal Labor	192(25.6)	34(23.0)	NS

TABLE 3
Analgesia/Anesthesia

	(N = 741) 20-35 lbs NO (%)	(N = 147) >35 lbs NO (%)	p
Meperidine	150(20.2)	36(24.5)	NS
Local	240(32.4)	49(33.3)	NS
Pudendal	149(20.1)	31(21.1)	NS
Epidural	83(11.2)	20(13.6)	NS

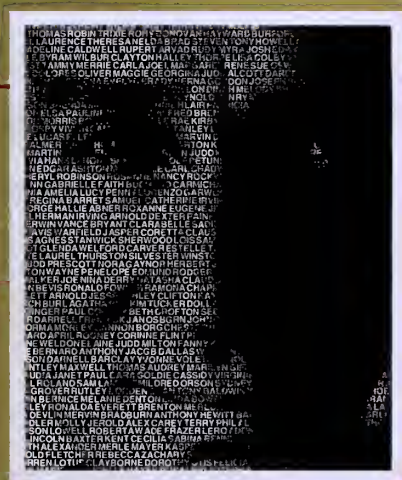
TABLE 4
Delivery Variables

	(N = 750) 20-35 lbs NO (%)	(N = 148) >35 lbs NO (%)	p
Episiotomy	442(58.9)	94(63.5)	NS
Assisted Delivery	106(14.1)	24(16.2)	NS
Primary C-Section	80(10.7)	30(20.3)	<.005

continued on page 25

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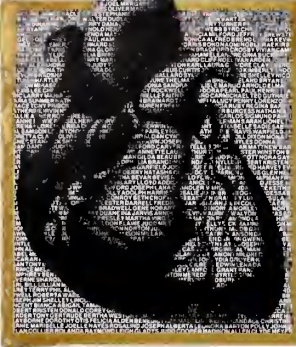
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BRIEF SUMMARY (FOR FULL PRESCRIBING INFORMATION, SEE PACKAGE CIRCULAR.)

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DESCRIPTION. Inderal LA is formulated to provide a sustained release of propranolol hydrochloride. Inderal LA is available as 60 mg, 80 mg, 120 mg, and 160 mg capsules.

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• Inderal LA Capsules (60, 80, 120, and 160 mg) release propranolol HCl at a controlled and predictable rate. Peak blood levels following dosing with Inderal LA occur at about 6 hours and the apparent plasma half-life is about 10 hours. When measured at steady state over a 24-hour period the areas under the propranolol plasma concentration-time curve (AUCs) for the capsules are approximately 60% to 65% of the AUCs for a comparable divided daily dose of Inderal Tablets. The lower AUCs for the capsules are due to greater hepatic metabolism of propranolol, resulting from the slower rate of absorption of propranolol. Over a twenty-four (24) hour period, blood levels are fairly constant for about twelve (12) hours then decline exponentially.

Inderal LA should not be considered a simple mg-for-mg substitute for conventional propranolol and the blood levels achieved do not match (are lower than) those of two to four times daily dosing with the same dose. When changing to Inderal LA from conventional propranolol, a possible need for retitration upwards should be considered especially to maintain effectiveness at the end of the dosing interval. In most clinical settings, however, such as hypertension or angina where there is little correlation between plasma levels and clinical effect, Inderal LA has been therapeutically equivalent to the same mg dose of conventional Inderal as assessed by 24-hour effects on blood pressure and on 24-hour exercise responses of heart rate, systolic pressure, and rate pressure product. Inderal LA can provide effective beta blockade for a 24-hour period.

INDICATIONS AND USAGE. **Hypertension:** Inderal LA is indicated in the management of hypertension; it may be used alone or used in combination with other antihypertensive agents, particularly a thiazide diuretic. Inderal LA is not indicated in the management of hypertensive emergencies.

Angina Pectoris Due to Coronary Atherosclerosis: Inderal LA is indicated for the long-term management of patients with angina pectoris.

Migraine: Inderal LA is indicated for the prophylaxis of common migraine headache. The efficacy of propranolol in the treatment of a migraine attack that has started has not been established and propranolol is not indicated for such use.

Hypertrophic Subaortic Stenosis: Inderal LA is useful in the management of hypertrophic subaortic stenosis, especially for treatment of exertional or other stress-induced angina, palpitations, and syncope. Inderal LA also improves exercise performance. The effectiveness of propranolol hydrochloride in this disease appears to be due to a reduction of the elevated outflow pressure gradient which is exacerbated by beta-receptor stimulation. Clinical improvement may be temporary.

CONTRAINDICATIONS. Inderal is contraindicated in 1) cardiogenic shock; 2) sinus bradycardia and greater than first-degree block; 3) bronchial asthma; 4) congestive heart failure (see WARNINGS) unless the failure is secondary to a tachyarrhythmia treatable with Inderal.

WARNINGS. **CARDIAC FAILURE:** Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive heart failure, and its inhibition by beta blockade may precipitate more severe failure. Although beta blockers should be avoided in overt congestive heart failure, if necessary, they can be used with close follow-up in patients with a history of failure who are well compensated and are receiving digitalis and diuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitalis on heart muscle.

IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta blockers can, in some cases, lead to cardiac failure. Therefore, at the first sign or symptom of heart failure, the patient should be digitalized and/or treated with diuretics, and the response observed closely, or Inderal should be discontinued (gradually, if possible).

IN PATIENTS WITH ANGINA PECTORIS, there have been reports of exacerbation of angina and, in some cases, myocardial infarction, following abrupt discontinuance of Inderal therapy. Therefore, when discontinuance of Inderal is planned, the dosage should be gradually reduced over at least a few weeks, and the patient should be cautioned against interruption or cessation of therapy without the physician's advice. If Inderal therapy is interrupted and exacerbation of angina occurs, it is usually advisable to reinstitute Inderal therapy and take other measures appropriate for the management of unstable angina pectoris. Since coronary artery disease may be unrecognized, it may be prudent to follow the above advice in patients considered at risk of having occult atherosclerotic heart disease who are given propranolol for other indications.

Nonallergic Bronchospasm (eg, chronic bronchitis, emphysema)—PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD IN GENERAL NOT RECEIVE BETA BLOCKERS. Inderal should be administered with caution since it may block bronchodilation produced by endogenous and exogenous catecholamine stimulation of beta receptors.

MAJOR SURGERY: The necessity or desirability of withdrawal of beta-blocking therapy prior to major surgery is controversial. It should be noted, however, that the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.

Inderal (propranolol HCl), like other beta blockers, is a competitive inhibitor of beta-receptor agonists and its effects can be reversed by administration of such agents, eg, dobutamine or isoproterenol. However, such patients may be subject to protracted severe hypotension. Difficulty in starting and maintaining the heartbeat has also been reported with beta blockers.

DIABETES AND HYPOLYCEMIA: Beta blockers should be used with caution in diabetic patients if a beta-blocking agent is required. Beta blockers may mask tachycardia occurring with hypoglycemia, but other manifestations such as dizziness and sweating may not be significantly affected. Following insulin-induced hypoglycemia, propranolol may cause a delay in the recovery of blood glucose to normal levels.

THYROTOXICOSIS: Beta blockade may mask certain clinical signs of hyperthyroidism. Therefore, abrupt withdrawal of propranolol may be followed by an exacerbation of symptoms of hyperthyroidism, including thyroid storm. Propranolol may change thyroid function tests, increasing T_4 and reverse T_3 , and decreasing T_3 .

IN PATIENTS WITH WOLFF-PARKINSON-WHITE SYNDROME, several cases have been reported in which, after propranolol, the tachycardia was replaced by a severe bradycardia requiring a demand pacemaker. In one case this resulted after an initial dose of 5 mg propranolol.

PRECAUTIONS. **GENERAL:** Propranolol should be used with caution in patients with impaired hepatic or renal function. Inderal (propranolol HCl) is not indicated for the treatment of hypertensive emergencies.

Beta-adrenoreceptor blockade can cause reduction of intraocular pressure. Patients should be told that Inderal may interfere with the glaucoma screening test. Withdrawal may lead to a return of increased intraocular pressure.

CLINICAL LABORATORY TESTS: Elevated blood urea levels in patients with severe heart disease, elevated serum transaminase, alkaline phosphatase, lactate dehydrogenase.

DRUG INTERACTIONS: Patients receiving catecholamine-depleting drugs such as reserpine should be closely observed if Inderal (propranolol HCl) is administered. The added catecholamine-blocking action may produce an excessive reduction of resting sympathetic nervous activity which may result in hypotension, marked bradycardia, vertigo, syncopal attacks, or orthostatic hypotension.

Caution should be exercised when patients receiving a beta blocker are administered a calcium-channel-blocking drug, especially intravenous verapamil, for both agents may depress myocardial contractility or atrioventricular conduction. On rare occasions, the concomitant intravenous use of a beta blocker and verapamil has resulted in serious adverse reactions, especially in patients with severe cardiomyopathy, congestive heart failure, or recent myocardial infarction.

Aluminum hydroxide gel greatly reduces intestinal absorption of propranolol.

Ethanol slows the rate of absorption of propranolol.

Phenytoin, phenobarbital, and rifampin accelerate propranolol clearance.

Chlorpromazine, when used concomitantly with propranolol, results in increased plasma levels of both drugs.

Antipyrine and lidocaine have reduced clearance when used concomitantly with propranolol.

Thyroxine may result in a lower than expected T_3 concentration when used concomitantly with propranolol.

Cimetidine decreases the hepatic metabolism of propranolol, delaying elimination and increasing blood levels.

Theophylline clearance is reduced when used concomitantly with propranolol.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY: Long-term studies in animals have been conducted to evaluate toxic effects and carcinogenic potential. In 18-month studies in both rats and mice, employing doses up to 150 mg/kg day, there was no evidence of significant drug-induced toxicity. There were no drug-related tumorigenic effects at any of the dosage levels. Reproductive studies in animals did not show any impairment of fertility that was attributable to the drug.

PREGNANCY: Pregnancy Category C. Inderal has been shown to be embryotoxic in animal studies at doses about 10 times greater than the maximum recommended human dose.

There are no adequate and well-controlled studies in pregnant women. Inderal should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

NURSING MOTHERS: Inderal is excreted in human milk. Caution should be exercised when Inderal is administered to a nursing woman.

PEDIATRIC USE: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS. Most adverse effects have been mild and transient and have rarely required the withdrawal of therapy.

Cardiovascular: Bradycardia; congestive heart failure; intensification of AV block; hypotension; paresthesia of hands; thrombocytopenic purpura; arterial insufficiency, usually of the Raynaud type.

Central Nervous System: Light-headedness; mental depression manifested by insomnia, lassitude, weakness, fatigue; reversible mental depression progressing to cataplexy; visual disturbances; hallucinations; vivid dreams; an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics. For immediate formulations, fatigue, lethargy, and vivid dreams appear dose related.

Gastrointestinal: Nausea, vomiting, epigastric distress, abdominal cramping, diarrhea, constipation, mesenteric arterial thrombosis, ischemic colitis.

Allergic: Pharyngitis and agranulocytosis, erythematous rash, fever combined with aching and sore throat, laryngospasm and respiratory distress.

Respiratory: Bronchospasm.

Hematologic: Agranulocytosis, nonthrombocytopenic purpura, thrombocytopenic purpura.

Auto-Immune: In extremely rare instances, systemic lupus erythematosus has been reported.

Miscellaneous: Alopecia, LE-like reactions, psoriasisiform rashes, dry eyes, male impotence, and Peyronie's disease have been reported rarely. Oculomucocutaneous reactions involving the skin, serous membranes and conjunctivae reported for a beta blocker (practolol) have not been associated with propranolol.

DOSAGE AND ADMINISTRATION. Inderal LA provides propranolol hydrochloride in a sustained-release capsule for administration once daily. If patients are switched from Inderal Tablets to Inderal LA Capsules, care should be taken to assure that the desired therapeutic effect is maintained. Inderal LA should not be considered a simple mg-for-mg substitute for Inderal. Inderal LA has different kinetics and produces lower blood levels. Retitration may be necessary, especially to maintain effectiveness at the end of the 24-hour dosing interval.

HYPERTENSION—Dosage must be individualized. The usual initial dosage is 80 mg Inderal LA once daily, whether used alone or added to a diuretic. The dosage may be increased to 120 mg once daily or higher until adequate blood pressure control is achieved. The usual maintenance dosage is 120 to 160 mg once daily. In some instances a dosage of 640 mg may be required. The time needed for full hypertensive response to a given dosage is variable and may range from a few days to several weeks.

ANGINA PECTORIS—Dosage must be individualized. Starting with 80 mg Inderal LA once daily, dosage should be gradually increased at three- to seven-day intervals until optimal response is obtained. Although individual patients may respond at any dosage level, the average optimal dosage appears to be 160 mg once daily. In angina pectoris, the value and safety of dosage exceeding 320 mg per day have not been established.

If treatment is to be discontinued, reduce dosage gradually over a period of a few weeks (see WARNINGS).

MIGRAINE—Dosage must be individualized. The initial oral dose is 80 mg Inderal LA once daily. The usual effective dose range is 160-240 mg once daily. The dosage may be increased gradually to achieve optimal migraine prophylaxis. If a satisfactory response is not obtained within four to six weeks after reaching the maximal dose, Inderal LA therapy should be discontinued. It may be advisable to withdraw the drug gradually over a period of several weeks.

HYPERTROPHIC SUBAORTIC STENOSIS—80-160 mg Inderal LA once daily.

PEDIATRIC DOSAGE—At this time the data on the use of the drug in this age group are too limited to permit adequate directions for use.

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Reference:

1. Data on file, Ayerst Laboratories.

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Excessive Weight Gain

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Results

Of the total sample, 97 (9.7%) gained <20, 750 (75.4%) gained 20-35 pounds, and 148 (14.9) gained >35 pounds. This analysis included only the latter two groups. The groups were of similar gestational age, with a preponderance of primiparas in the high weight gain category, as shown in Table 1. Post dates pregnancies demonstrated a non-significant trend towards an increase in the high weight gain group. Diabetes of any class was a very low frequency finding, and hypertensive disorders were significantly increased in the high weight gain group. Further analysis revealed that this difference was confined to toxemia, with no significant difference noted in chronic hypertension or combined acute and chronic hypertension.

The pertinent labor variables are summarized in Table 2, showing only a significant increase in oxytocin augmentation in the high weight gain group. When multiparas were analyzed separately, there was also no difference in labor abnormalities, including protraction or arrest of dilatation and protraction or arrest of descent. Table 3 lists the choices of pain relief for labor and delivery, with no significant difference noted.

The delivery variables are shown in Table 4, with the marked increase in primary cesarean section apparent in the high weight gain group. The infant outcome variables summarized in Table 5 show the clear increase in macrosomic infants in the high weight gain group.

When groups were stratified by parity, the increase in augmentation was significant only in multiparas, and the differences in hypertension, primary cesarean section, and macrosomia was found only in primiparas, as shown in Table 6. No new variables became significant in this secondary analysis. The apparent paradox that primiparas had more C-sections and macrosomic infants without an increase in FHR abnormalities or abnormal labor was also addressed in further analysis. While there was no trend in labor abnormalities in multiparas, the heavier weight gain primiparas did show an increase in second stage abnormalities that was significant at the $p < .10$ level. Of the 27 primipara C-sections, 8 had an arrest of dilatation and 10 had an arrest of descent. It is possible that in a larger study these abnormalities of labor in primiparas would have reached significance at the $p < .05$ level.

Discussion

In this population of relatively unselected patients managed in small community hospitals, pregnancy weight gains exceeding 35 pounds were associated with increased augmentation in multiparas, and an increase in hypertension, infant macrosomia, and primary cesarean section in primiparas. The generaliza-

TABLE 5
Infant Outcome Variables

	(N = 734) 20-35 lbs NO (%)	(N = 144) >35 lbs NO (%)	p
FHR Abnormality	80(10.9)	20(13.9)	NS
Meconium Staining	38(5.2)	9(6.3)	NS
Wt <2500g	34(4.6)	3(2.1)	NS
Wt >4500g	9(1.2)	7(4.9)	<.01
1 Min APGAR <7	62(8.4)	13(9.0)	NS
5 Min APGAR <7	24(3.3)	3(2.1)	NS

TABLE 6
Subgroup Comparison

	(N = 898) Total Group p	(N = 475) Multips Only p	(N = 423) Primips Only p
Hypertension	<.001	>.10	<.001
Augmentation	<.05	<.05	NS
Primary C-Section	<.005	>.10	<.005
Wt >4500 g	<.01	>.10	<.05

bility of these data is enhanced by the composition of the study population, but the validity for some variables is limited by the variation in definitions. Standard definitions of diabetes and hypertension were presumably used, but these were not specified prior to data collection. However, the significant differences noted were in variables with clear end-points, and the criteria for labor abnormalities were established and printed on the data collection form.

A further limitation of this analysis is the lack of data on prepregnant weight and height. The prepregnant weight will often be missing in healthy women who do not seek prenatal care early. Height measurements are infrequently done, making precise body proportion calculations impractical. The clinician's estimate of net weight gain used in this study is most commonly based on the prenatal records, which would underestimate the actual weight gain in most circumstances. This would identify a clear high risk group gaining more than 35 pounds, and misclassify some potential high risk patients in the normal group. This decrease in sensitivity is balanced by an increase in specificity, which can be viewed as an advantage to the clinician.

The difference in diabetes noted previously in more selected populations can not be addressed in this study because of the low incidence in the study population. The increase in toxemia is similar to previous reports,

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Excessive Weight Gain

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but no increase in chronic hypertension was found. Cause and effect is difficult to ascertain in this situation, as it is not uncommon for a toxemic patient to gain 4-6 lb in the last few weeks of pregnancy. This would falsely classify a patient who had gained in the range of 30 lb prior to the acute onset of edema.

The increase in macrosomia reported previously was demonstrated in this study group also, but only the primiparas showed this difference. Even using the lower threshold of 4000g sometimes used in the literature, the difference in multiparas was not significant. There was no measure of birth trauma included in the data base. There was a trend towards a small increase in second stage abnormalities in primiparas, but none in multiparas as previously reported.

The results of this study suggest that excessive weight gain was a risk factor in this unselected population. However, this risk is limited to hypertension, macrosomia, and increased primary C-section in primiparas, and the potential hazards of labor augmentation in multiparas.

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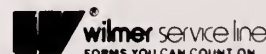
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Hyperthermia in the Treatment of Cancer

John A. Pinkston, M.D.*

Abstract

Hyperthermia — the elevation of temperature above normal levels — is emerging as a useful modality in the treatment of cancer, with progress being made both technologically and in defining clinical indications for its use.

Irradiation *in vitro* of cells which have been heated to temperatures of 42-43° C produces an enhanced cell kill compared with irradiation alone. The cellular mechanisms involve damage at multiple levels, including membranes, nucleus, and cytoplasm. Solid tumors are also heat sensitive due to the defective microvasculature of the tumor.

Various methods are used to produce hyperthermia at therapeutic levels. Local, superficial heating is accomplished by externally applied applicators or interstitial probes inserted into tumor tissue. Regional hyperthermia of extremity lesions or for deep-seated abdominal and pelvic tumors is accomplished using externally applied devices or perfusion techniques. Most methods use ultrasound or electromagnetic radiation at microwave fre-

quency or radiofrequency to produce heat. Devices suitable for use in radiation therapy departments have been approved by the U.S. Food and Drug Administration and are commercially available.

Clinical studies indicate that in selected cases, the combination of hyperthermia to radiotherapy can produce improvement in response rates. Some studies have demonstrated an approximate doubling of the complete response rate in superficial tumors. For heating of deep-seated pelvic and abdominal tumors, studies have shown promise, but technical problems remain with effective delivery of heat and its accurate measurement. Whole body hyperthermia is also under investigation.

Current indications for hyperthermia are mostly limited to its combined use with radiotherapy in the treatment of superficial tumors that have recurred following conventional therapy. Examples are masses of lymph nodes in the neck from head and neck cancer, and chest wall recurrences following treatment for cancer of the breast. Use of hyperthermia with conventional therapies to improve outcomes remains investigational, but shows considerable promise.

* Director, Department of Radiation Therapy and Clinical Hyperthermia Unit, Gordon L. Ross Cancer Center, Baptist Medical Center Princeton, 801 Princeton Avenue SW, Birmingham, AL 35211. Clinical Associate Professor of Radiation Oncology, University of Alabama, Birmingham.

Introduction

Hyperthermia — the elevation of temperature above normal levels — is emerging as a useful modality in the treatment of malignant diseases. Laboratory research has provided a rational foundation for its use, and clinical studies have shown that partial and complete tumor responses are possible. Its greatest value currently lies in its combination with radiation therapy, although optimism exists for its future use with chemotherapy as well. Hyperthermia is becoming more available in community hospitals. The purpose of this report is to briefly review the current status of hyperthermia, and to outline some of the indications for its use.

Historical Perspective

Although heat for the treatment of diseases in humans has been applied in various forms for centuries, interest in its use for the treatment of cancer was first recorded in the medical literature in the middle of the 19th century,¹ in which the disappearance of a sarcoma following high fever in a patient with erysipelas was described. Around the turn of the century, Coley²⁻⁴ induced fever in cancer patients by the administration of pyrogenic bacterial toxins. Several of the patients improved, and these early results stimulated continued interest in heat as a form of cancer therapy. In 1935, Warren⁵ reported the results of using whole body hyperthermia in 32 patients with advanced cancers. Patients' temperatures were elevated using a combination of diathermy and light bulbs in a heating cabinet. Although no cures resulted, he believed that improvement had occurred in many of the patients, with varying degrees of shrinkage of the tumors. He encouraged further research in hyperthermia.

Subsequent laboratory experiments showed that heat alone or in combination with radiotherapy could result in control of transplanted tumors in mice.^{6, 7} While advances were made in radiation therapy and chemotherapy, progress in the use of hyperthermia was hampered by the slow development of adequate technology for heat delivery and measurement. With the advent in the last 2-3 decades of improved technology, along with advances in tumor and radiation biology, a scientific basis for hyperthermia has emerged. This, coupled with increasing evidence from clinical studies of potential benefit to patients, has led to renewed interest in hyperthermia alone and in combination with radiotherapy and chemotherapy. Historical reviews of the early clinical use of hyperthermia are available.^{8, 9}

Biologic Rationale

Extensive laboratory research has provided a firm biological basis for the use of heat in cancer therapy.

Cellular studies *in vitro* have shown that hyperthermia kills cells exponentially as a function of time at temperatures above 42 °C.⁸ Cells are most sensitive during the DNA synthetic phase of the cell cycle,¹⁰ and hyperthermia selectively kills relatively radioresistant hypoxic and nutritionally deprived cells at low pH, such as tumor cells often found in or near necrotic areas of tumors.^{11, 12} These characteristics make hyperthermia complementary to radiotherapy, which is most effective during the mitotic phase of the cell cycle, and against cells which are well oxygenated and at normal pH. Hyperthermia has also been shown to interact synergistically with ionizing radiation¹³ and with certain chemotherapeutic drugs.¹⁴ In addition to these *in vitro* cellular studies, tumor cytotoxicity^{6, 15} and radiosensitization^{16, 17} by hyperthermia has been documented *in vivo* in laboratory animals, and pet animals have been treated using heat alone and in combination with radiotherapy.^{18, 19}

The mechanisms by which heat exerts its effects at the cellular level appear to involve both the cellular membranes²⁰ and nucleus.²¹ Heat markedly affects cell membranes, influencing transport of molecules into the cell and impairing the function of cytoplasmic organelles, such as lysosomes and mitochondria. Following heat exposure, there is a large increase in the amount of nonhistone nuclear protein, which is thought to adversely affect DNA supercoiling and restrict access to DNA of DNA-active enzymes. The level of cell kill is positively correlated with the amount of these accumulated proteins. DNA synthesis is inhibited for several hours after heat exposure, and studies have shown interference with replicon initiation and DNA chain elongation.

Physiological properties of tumors, such as aberrant tumor vasculature, also influence the response to heat.^{22, 23} The normal physiological response to heat results in increased blood flow to dissipate the heat stress. In some tumors, the vasculature is deficient when compared to the normal vasculature of surrounding tissues. This, coupled with the lack of effective thermoregulatory reflexes, may lead to preferential tumor heating. Tumor microvasculature has been shown to be more sensitive to heat than normal microvasculature, and may undergo collapse and irreversible damage following hyperthermic treatment; this is thought to be an important mechanism of tumor cytotoxicity.

After exposure to therapeutic levels of heat (above 42° C), cells become resistant to the further effects of heat. This phenomenon, called *thermal tolerance*, is time dependent and decays over a period of 36-72 hours, after which the thermal response is normal again. The mechanisms are not well understood, but are thought to be related to "heat shock" proteins produced in response to hyperthermic exposure.^{21, 24}

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Before prescribing, see complete prescribing information in SK&F LAB CO. literature or PDR. The following is a brief summary.

Contraindications: There are no known contraindications to the use of 'Tagamet'.

Precautions: While a weak antiandrogenic effect has been demonstrated in animals, 'Tagamet' has been shown to have no effect on spermatogenesis, sperm count, motility, morphology or in vitro fertilizing capacity in humans.

In a 24-month toxicity study in rats at dose levels approximately 9 to 56 times the recommended human dose, benign Leydig cell tumors were seen. These were common in both the treated and control groups, and the incidence became significantly higher only in the aged rats receiving 'Tagamet'.

Rare instances of cardiac arrhythmias and hypotension have been reported following the rapid administration of 'Tagamet' HCl (brand of cimetidine hydrochloride) injection by intravenous bolus.

Symptomatic response to 'Tagamet' therapy does not preclude the presence of a gastric malignancy. There have been rare reports of transient healing of gastric ulcers despite subsequently documented malignancy.

Reversible confusional states have been reported on occasion, predominantly in severely ill patients.

'Tagamet' has been reported to reduce the hepatic metabolism of warfarin-type anticoagulants, phenytoin, propranolol, chlorthalidone, diazepam, lidocaine, theophylline and metronidazole. Clinically significant effects have been reported with the warfarin anticoagulants; therefore, close monitoring of prothrombin time is recommended, and adjustment of the anticoagulant dose may be necessary when 'Tagamet' is administered concomitantly. Interaction with phenytoin, lidocaine and theophylline has also been reported to produce adverse clinical effects.

However, a crossover study in healthy subjects receiving either 'Tagamet' 300 mg. q.i.d. or 800 mg. h.s. concomitantly with a 300 mg. b.i.d. dosage of theophylline (Theo-Dur®, Key Pharmaceuticals, Inc.),

demonstrated less alteration in steady-state theophylline peak serum levels with the 800 mg. h.s. regimen, particularly in subjects aged 54 years and older. Data beyond ten days are not available. [Note: All patients receiving theophylline should be monitored appropriately, regardless of concomitant drug therapy.]

Lack of experience to date precludes recommending 'Tagamet' for use in pregnant patients, women of childbearing potential, nursing mothers or children under 16 unless anticipated benefits outweigh potential risks; generally, nursing should not be undertaken in patients taking the drug since cimetidine is secreted in human milk.

Adverse Reactions: Diarrhea, dizziness, somnolence, headache, rash. Reversible arthralgia, myalgia and exacerbation of joint symptoms in patients with preexisting arthritis have been reported. Reversible confusional states [e.g., mental confusion, agitation, psychosis, depression, anxiety, hallucinations, disorientation], predominantly in severely ill patients, have been reported. Gynecomastia and reversible impotence in patients with pathological hypersecretory disorders receiving 'Tagamet', particularly in high doses, for at least 12 months, have been reported. Reversible alopecia has been reported very rarely. Decreased white blood cell counts in 'Tagamet'-treated patients [approximately 1 per 100,000 patients], including agranulocytosis [approximately 3 per million patients], have been reported, including a few reports of recurrence on rechallenge. Most of these reports were in patients who had serious concomitant illnesses and received drugs and/or treatment known to produce neutropenia. Thrombocytopenia [approximately 3 per million patients] and a few cases of aplastic anemia have also been reported. Increased serum transaminase and creatinine, as well as rare cases of fever, interstitial nephritis, urinary retention, pancreatitis and allergic reactions, including hypersensitivity vasculitis, have been reported. Reversible adverse hepatic effects, cholestatic or mixed cholestatic-hepatocellular in nature, have been reported rarely. Because of the predominance of cholestatic features, severe parenchymal injury is considered highly un-

likely. A single case of biopsy-proven periportal hepatic fibrosis in a patient receiving 'Tagamet' has been reported.

How Supplied: Tablets: 200 mg. tablets in bottles of 100; 300 mg. tablets in bottles of 100 and Single Unit Packages of 100 [intended for institutional use only]; 400 mg. tablets in bottles of 60 and Single Unit Packages of 100 [intended for institutional use only], and 800 mg. Tiltab® tablets in bottles of 30 and Single Unit Packages of 100 [intended for institutional use only].

Liquid: 300 mg./5 ml., in 8 fl. oz. (237 ml.) amber glass bottles and in single-dose units (300 mg./5 ml.), in packages of 10 [intended for institutional use only].

Injection:

Vials: 300 mg./2 ml. in single-dose vials, in packages of 10 and 30, and in 8 ml. multiple-dose vials, in packages of 10 and 25.

Prefilled Syringes: 300 mg./2 ml. in single-dose prefilled disposable syringes.

Plastic Containers: 300 mg. in 50 ml. of 0.9% Sodium Chloride in single-dose plastic containers, in packages of 4 units. No preservative has been added.

ADD-Vantage® Vials: 300 mg./2 ml. in single-dose, ADD-Vantage® Vials, in packages of 25.

Exposure of the premixed product to excessive heat should be avoided. It is recommended the product be stored at controlled room temperature. Brief exposure up to 40°C does not adversely affect the premixed product.

'Tagamet' HCl (brand of cimetidine hydrochloride) Injection premixed in single-dose plastic containers is manufactured for SK&F Lab Co. by Travenol Laboratories, Inc., Deerfield, IL 60015.

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BRS-TG-L73B

Date of Issuance Apr. 1987

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* Not for initial therapy. See brief summary.

Before prescribing, see complete
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The following is a brief summary.

WARNING

This drug is not indicated for initial therapy of edema or hypertension. Edema or hypertension requires therapy titrated to the individual. If this combination represents the dosage so determined, its use may be more convenient in patient management. Treatment of hypertension and edema is not static, but must be reevaluated as conditions in each patient warrant.

Contraindications: Concomitant use with other potassium-sparing agents such as spironolactone or amiloride. Further use in anuria, progressive renal or hepatic dysfunction, hyperkalemia. Pre-existing elevated serum potassium. Hypersensitivity to either component or other sulfonamide-derived drugs.

Warnings: Do not use potassium supplements, dietary or otherwise, unless hypokalemia develops or dietary intake of potassium is markedly impaired. If supplementary potassium is needed, potassium tablets should not be used. Hyperkalemia can occur, and has been associated with cardiac irregularities. It is more likely in the severely ill, with urine volume less than one liter/day, the elderly and diabetics with suspected or confirmed renal insufficiency. Periodically, serum K⁺ levels should be determined. If hyperkalemia develops, substitute a thiazide alone, restrict K⁺ intake. Associated widened QRS complex or arrhythmia requires prompt additional therapy. Thiazides cross the placental barrier and appear in cord blood. Use in pregnancy requires weighing anticipated benefits against possible hazards, including fetal or neonatal jaundice, thrombocytopenia, other adverse reactions seen in adults. Thiazides appear and triamterene may appear in breast milk. If their use is essential, the patient should stop nursing. Adequate information on use in children is not available. Sensitivity reactions may occur in patients with or

without a history of allergy or bronchial asthma. Possible exacerbation or activation of systemic lupus erythematosus has been reported with thiazide diuretics.

Precautions: The bioavailability of the hydrochlorothiazide component of 'Dyazide' is about 50% of the bioavailability of the single entity. Theoretically, a patient transferred from the single entities of triamterene and hydrochlorothiazide may show an increase in blood pressure or fluid retention. Similarly, it is also possible that the lesser hydrochlorothiazide bioavailability could lead to increased serum potassium levels. However, extensive clinical experience with 'Dyazide' suggests that these conditions have not been commonly observed in clinical practice. Angiotensin-converting enzyme (ACE) inhibitors can elevate serum potassium; use with caution with 'Dyazide'. Do periodic serum electrolyte determinations (particularly important in patients vomiting excessively or receiving parenteral fluids, and during concurrent use with amphotericin B or corticosteroids or corticotropin [ACTH]). Periodic BUN and serum creatinine determinations should be made, especially in the elderly, diabetics or those with suspected or confirmed renal insufficiency. Cumulative effects of the drug may develop in patients with impaired renal function. Thiazides should be used with caution in patients with impaired hepatic function. They can precipitate coma in patients with severe liver disease. Observe regularly for possible blood dyscrasias, liver damage, other idiosyncratic reactions. Blood dyscrasias have been reported in patients receiving triamterene, and leukopenia, thrombocytopenia, agranulocytosis, and aplastic and hemolytic anemia have been reported with thiazides. Thiazides may cause manifestation of latent diabetes mellitus. The effects of oral anticoagulants may be decreased when used concurrently with hydrochlorothiazide; dosage adjustments may be necessary. Clinically insignificant reductions in arterial responsiveness to norepinephrine have been reported. Thiazides have also been shown to increase the paralyzing effect of nondepolarizing muscle relaxants such as tubocurarine. Triamterene is a weak folic acid antagonist. Do periodic blood studies in cirrhotics with splenomegaly. Antihypertensive effects may be enhanced in post-sympathectomy patients. Use cautiously in surgical patients. Triamterene has been found in renal stones in association with the other usual calculus components. Therefore, 'Dyazide' should be used with caution in patients with histories of stone formation. A few occurrences of acute renal failure have been reported in patients on 'Dyazide' when treated with indomethacin. Therefore, caution is advised in administering nonsteroidal anti-inflammatory agents with 'Dyazide'. The

following may occur: transient elevated BUN or creatinine or both, hyperglycemia and glycosuria (diabetic insulin requirements may be altered), hyperuricemia and gout, digitalis intoxication (in hypokalemia), decreasing alkali reserve with possible metabolic acidosis. 'Dyazide' interferes with fluorescent measurement of quinidine. Hypokalemia is uncommon with 'Dyazide', but should it develop, corrective measures should be taken such as potassium supplementation or increased dietary intake of potassium-rich foods. Corrective measures should be instituted cautiously and serum potassium levels determined. Discontinue corrective measures and 'Dyazide' should laboratory values reveal elevated serum potassium. Chloride deficit may occur as well as dilutional hyponatremia. Concurrent use with chlorpropamide may increase the risk of severe hyponatremia. Serum PBI levels may decrease without signs of thyroid disturbance. Calcium excretion is decreased by thiazides. 'Dyazide' should be withdrawn before conducting tests for parathyroid function. Thiazides may add to or potentiate the action of other antihypertensive drugs. Diuretics reduce renal clearance of lithium and increase the risk of lithium toxicity.

Adverse Reactions: Muscle cramps, weakness, dizziness, headache, dry mouth; anaphylaxis, rash, urticaria, photosensitivity, purpura, other dermatological conditions; nausea and vomiting, diarrhea, constipation, other gastrointestinal disturbances; postural hypotension (may be aggravated by alcohol, barbiturates, or narcotics). Necrotizing vasculitis, paresthesias, icterus, pancreatitis, xanthopsia and respiratory distress including pneumonitis and pulmonary edema, transient blurred vision, sialadenitis, and vertigo have occurred with thiazides alone. Triamterene has been found in renal stones in association with other usual calculus components. Rare incidents of acute interstitial nephritis have been reported. Impotence has been reported in a few patients on 'Dyazide', although a causal relationship has not been established.

Supplied: 'Dyazide' is supplied as a red and white capsule, in bottles of 1000 capsules; Single Unit Packages (unit-dose) of 100 (intended for institutional use only); in Patient-Pak™ unit-of-use bottles of 100.

BR5-D2:L45

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Physical Methods to Achieve Hyperthermia

Various methods have been used to produce hyperthermia. For the heating of relatively superficial tumors, such as enlarged masses of lymph nodes in the neck, or recurrences of cancer of the breast on the chest wall after mastectomy, the electronically based methods have generally found more favor than the direct application of heat, such as a water bath or jet of heated air. The two most common types are: (1) electromagnetic wave devices, which use microwaves in the frequency range 300-3000 MegaHertz (MHz), or radio-frequency (RF) waves of 5-50 MHz, and, (2) ultrasound devices, which use vibrational-mechanical energy of 1-3 MHz. These methods employ non-invasive applicators which are positioned over the region to be treated, and are spatially arranged to achieve a uniform heating pattern through the volume of tissue to be treated. More invasive techniques are also used, such as interstitial implantation of needles which heat as a result of the passage of an electromagnetic current, and interstitial or intracavitary insertion of small antennae which emit electromagnetic waves. Another approach uses the implantation of ferromagnetic seeds, which produce heat when "excited" by an externally applied magnetic field.

For deep-seated pelvic or intra-abdominal tumors requiring regional hyperthermia, heating is more complex. One method has been the Magnetron (Henry Medical Electronics, Los Angeles, CA) which employs a circumferential coil for induction of electromagnetic energy at 13.56 MHz.²⁵ Another approach, called the annular phased array,²⁶ employs an octagonal, circumferential array of several electromagnetic wave guides. Electromagnetic waves at 55-110 MHz are generated and the applicators operated in phase with focusing of the resultant energy deposition pattern. The applicators are externally applied in both Magnetron and annular phased array methods.

The various approaches to achieve whole body hyperthermia include extracorporeal hyperthermic circulation, immersion of the patient in a wax bath, wrapping the patient in heated blankets, and the circulation of heated water through specially adapted "space suits."²⁷

Clinical Results

Superficial Tumors

Overgaard²⁸ summarized the results obtained in the treatment of over 3000 patients in 66 different studies published from 1977-1980. Most patients had superficial lesions, and among 276 patients treated with hyperthermia alone the overall response rate was 52%, with a complete response observed in 13%, partial response in 39%, and no response in 48%. Similar results for hyperthermia alone were reported by Mar-

Several studies have compared irradiation along with irradiation plus hyperthermia.³⁰⁻³⁶ An approximate doubling of the complete response rate was observed in most of the studies for radiotherapy combined with hyperthermia compared to radiotherapy alone. The results are summarized in Table 1. Most patients had received extensive prior radiotherapy and chemotherapy, which had failed to achieve local control. The wide spectrum of tumor sites in comparable patients represented in these studies provide substantial clinical evidence of the efficacy of hyperthermia combined with irradiation. In these studies, it was found that temperature elevations to 42-43° C for at least 30-45 minutes were required to produce the tumoricidal effect, which focuses attention on the importance of accurate thermometry (temperature measurement).

Interstitial Hyperthermia

A few studies have been reported in which interstitially applied applicators were used to produce hyperthermia, combined with either interstitial or external beam radiotherapy.³⁷⁻⁴⁰ The results are summarized in Table 2. The complete response rate is comparable to that achieved with externally applied applicators and external irradiation.

Deep Regional Hyperthermia

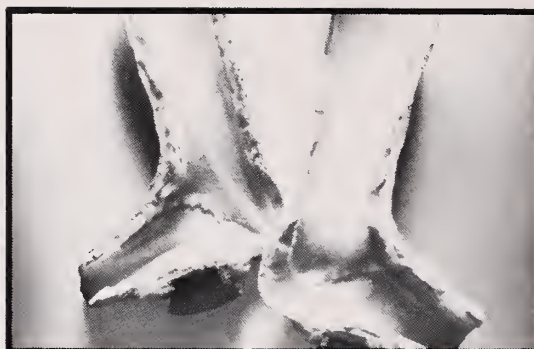
Few studies are available to assess the efficacy of hyperthermia for deep-seated tumors, due to the inherent problems of access to the tumor for placement of thermometry probes, and the complexities of achieving adequate heating. Storm et al⁴¹ have published results of a 5-year multi-institutional cooperative trial in which the Magnetron was used for heating. The trial involved Phase I-II studies of efficacy and safety in 1170 adult patients with advanced tumors, with 14,807 treatments being performed. Various temperatures and combinations of radiotherapy and chemotherapy were used. The median duration of response was 3-7 months (range 1-39 months). The authors concluded that hyperthermia has a significant role in the palliation of advanced malignancies and that prospective randomized Phase III trials are warranted.

Baker et al⁴² reported on a group of 107 patients with a variety of tumors treated with an induction coil and with either radiotherapy or chemotherapy. A complete response in 16%, partial response in 52%, and no response in 32% was observed. Most responders and about 30% of nonresponders had pain relief.

Results of pilot studies using the annular phased array to treat patients with advanced tumors in the abdomen and pelvis have been reported.^{43, 44} Among 28 patients with advanced upper abdominal malignancy,⁴³ most of whom received concurrent low dose radiotherapy, the partial response rate was only 18%.

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The five partial responders had a significantly longer survival ($p=0.02$) than the 23 nonresponders, and 43% of patients achieved effective palliation. Systemic heat stress, characterized by signs such as tachycardia and increased systemic temperature, was the most frequent treatment limiting factor. Among 43 patients with deep-seated pelvic tumors,⁴⁴ an overall objective response rate of 49% was achieved in 39 evaluable patients. Five of the 19 responses were complete. The median survival of responders (10 months) was significantly longer ($p=0.0014$) than nonresponders (4 months).

Whole Body Hyperthermia

Whole body hyperthermia is beset by a number of complex problems which have precluded its widespread investigation. Due to central nervous system and hepatic toxicity, temperatures are limited to about 42° C or less. The treatment is expensive, and requires general anesthesia, usually for several hours. Significant risks exist, including death from treatment — related complications. Nevertheless, it has the potential of treating widespread gross and microscopic metastatic disease. A few reports have appeared in which patients were usually treated for 2 hours or more at

temperatures of 41.5°-42° C. Objective responses were seen, but were usually of short duration. The current status and future prospects of whole body hyperthermia have been reviewed, with further research encouraged.⁴⁵

Hyperthermia and Chemotherapy

While the combination of hyperthermia with chemotherapy is a logical extension of its use with radiotherapy, detailed experimental data are only available *in vitro*. Measurable thermal enhancement of cytotoxicity has been reported to occur with some commonly used drugs such as the alkylating agents, cisplatin and mitomycin-C, but not with others, such as 5-Fluorouracil and the vinca alkaloids. Most *in vivo* studies have been limited to animal models, and are inconclusive. In a recently reported Phase I-II multi-institutional study, whole body hyperthermia to 41.5° C was achieved using an extracorporeal circulation technique.⁴⁶ Various chemotherapeutic agents were used to treat a variety of advanced neoplasms. Most patients received more than one treatment, and the average length of the treatments was about 11 hours (range 2-44 hours). One hundred sixty-eight patients were

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treated, of whom 132 were evaluable for response. Although a 29% overall response rate was reported, most responses were of short duration, and the effect on survival was small. In addition, 20% of the patients died of treatment-related complications. Further research is needed to better define a role for whole body hyperthermia and chemotherapy.

One useful approach combining hyperthermia with chemotherapy has been employed in the treatment of melanoma involving limbs. Perfusion of chemotherapeutic agents in blood heated to approximately 43°C through the affected limb appears to be effective and relatively well tolerated in this group of patients.⁴⁷

Adverse Effects of Local and Regional Hyperthermia

The complications of local and regional hyperthermia have been relatively infrequent and manageable. In one series of 101 superficial sites treated with irradiation and heat,⁴⁸ 7% developed tumor necrosis with deep ulceration that did not heal spontaneously. Six percent developed second and third degree burns, most of which healed spontaneously in 8-12 weeks. Since most patients had received prior radiotherapy, subcutaneous fibrosis was seen in about 35%. In the multi-institutional trial reported by Storm et al.,⁴¹ thermal burns occurred in only 0.3% of treatments, and there were only two systemic complications, one patient developing peptic ulcer, and another lung fibrosis (0.01%). This low complication rate, however, was partially attributed to exclusion of patients known to be at increased risk of hyperthermia complications, such as those with circulatory compromise in the treatment field, or significant tumor fistulae. With improvements in thermometry, these already low complication rates will be expected to further decrease.

Community Hospital Hyperthermia

Hyperthermia devices approved by the U.S. Food and Drug Administration and suitable for use in community hospital radiation therapy departments have been developed by several manufacturers and are com-

mercially available. Most of these devices are designed for the treatment of relatively superficial sites, although some may be adapted for treatment of more deeply seated tumors. Most are equipped with detachable external applicators of a variety of sizes and shapes, which allow flexibility of use, and with probes for thermometry and interstitial hyperthermia. Hyperthermia treatments typically last from 30 minutes to an hour, and are administered twice a week due to thermal tolerance. They are normally given on an outpatient basis in conjunction with radiotherapy, with the two treatments being administered in immediate sequence for maximal synergistic effect. Sedation or anesthesia is not used, and patients are able to communicate any untoward effects, such as pain or the excessive sensation of heat.

TABLE 1

Complete Responses of Superficial Lesions to Irradiation and Irradiation Plus Hyperthermia

Study	Number of Tumors	Irradiation Alone (%)	Irradiation + Hyperthermia (%)
U et al ³⁰	14	1/7(40)	6/7(86)
Bede et al ³¹	19	0/8(0)	1/11(9)
Overgaard ³²	33	8/16(50)	11/17(65)
Kim et al ³³	159	24/73(33)	69/86(80)
Kim et al ³⁴	99	25/54(46)	31/45(69)
Arcangeli et al ³⁵	123	22/57(39)	50/66(76)
Corry et al ³⁶	34	0/13(0)	13/21(62)
	481	80/228(35)	181/253(72)

Interstitial hyperthermia can also be used with interstitial radiotherapy in selected cases. Usually, the same catheters which house the interstitially applied radioactive isotopes can be used for the interstitial hyperthermia applicators, thus adding little to the usual interstitial radiotherapy procedure.

The usual clinical indication for hyperthermia is for the palliative treatment of advanced, relatively superficial malignant disease which has failed conventional treatment with surgery, radiation therapy, and chemotherapy. Examples are: (1) enlarged masses of lymph nodes, such as occur in the cervical region in head and

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TABLE 2

Results of Interstitial Thermoradiotherapy

Study	Number of Tumors	Complete Response (%)	Partial Response (%)	No Response* (%)
Emami et al ³⁷	26	18 (69)	5 (19)	3 (12)
Cosset et al ³⁸	12	10 (83)	2 (17)	0 (0)
Surwit et al ³⁹	21	7 (33)	10 (48)	4 (19)
Vora et al ⁴⁰	15	11 (73)	1 (7)	3 (20)
	74	46 (62)	18 (24)	10 (14)

*Less than 50% regression



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(160 mg trimethoprim and 800 mg sulfamethoxazole/Roche)

Bactrim™ Pediatric

(40 mg trimethoprim and
200 mg sulfamethoxazole per 5 ml)



Please see summary of product information on following page.

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Before prescribing, please consult complete product information, a summary of which follows:

CONTRAINDICATIONS: Hypersensitivity to trimethoprim or sulfonamides, documented megaloblastic anemia due to folate deficiency, pregnancy at term and during the nursing period, infants less than two months of age.

WARNINGS: FATALITIES ASSOCIATED WITH THE ADMINISTRATION OF SULFONAMIDES, ALTHOUGH RARE, HAVE OCCURRED DUE TO SEVERE REACTIONS, INCLUDING STEVENS-JOHNSON SYNDROME, TOXIC EPIDERMAL NECROLYSIS, FULMINANT HEPATIC NECROSIS, AGRANULOCYTOSIS, APLASTIC ANEMIA AND OTHER BLOOD DYSCRASIAS.

BACTRIM SHOULD BE DISCONTINUED AT THE FIRST APPEARANCE OF SKIN RASH OR ANY SIGN OF ADVERSE REACTION. Clinical signs, such as rash, sore throat, fever, pallor, purpura or jaundice, may be early indications of serious reactions. In rare instances a skin rash may be followed by more severe reactions, such as Stevens-Johnson syndrome, toxic epidermal necrolysis, hepatic necrosis or serious blood disorder. Perform complete blood counts frequently.

BACTRIM SHOULD NOT BE USED IN THE TREATMENT OF STREPTOCOCCAL PHARYNGITIS. Clinical studies show that patients with group A β -hemolytic streptococcal tonsillopharyngitis have a greater incidence of bacteriologic failure when treated with Bactrim than with penicillin.

PRECAUTIONS: General. Give with caution to patients with impaired renal or hepatic function, possible folate deficiency (e.g., elderly, chronic alcoholics, patients on anticonvulsants, with malabsorption syndrome, or in malnutrition states) and severe allergies or bronchial asthma. In glucose-6-phosphate dehydrogenase deficient individuals, hemolysis may occur, frequently dose-related.

Use in the Elderly. May be increased risk of severe adverse reactions in elderly, particularly with complicating conditions, e.g., impaired kidney and/or liver function, concomitant use of other drugs. Severe skin reactions, generalized bone marrow suppression (see WARNINGS AND ADVERSE REACTIONS) or a specific decrease in platelets (with or without purpura) are most frequently reported severe adverse reactions in elderly. In those concurrently receiving certain diuretics, primarily thiazides, increased incidence of thrombocytopenia with purpura reported. Make appropriate dosage adjustments for patients with impaired kidney function (see DOSAGE AND ADMINISTRATION).

Use in the Treatment of Pneumocystis Carinii Pneumonitis in Patients with Acquired Immunodeficiency Syndrome (AIDS). Because of unique immune dysfunction, AIDS patients may not tolerate or respond to Bactrim in same manner as non-AIDS patients. Incidence of side effects, particularly rash, fever, leukopenia, with Bactrim in AIDS patients treated for *Pneumocystis carinii* pneumonitis reported to be greatly increased compared with incidence normally associated with Bactrim in non-AIDS patients.

Information for Patients. Instruct patients to maintain adequate fluid intake to prevent crystalluria and stone formation.

Laboratory Tests. Perform complete blood counts frequently; if a significant reduction in the count of any formed blood element is noted, discontinue Bactrim. Perform urinalyses with careful microscopic examination and renal function tests during therapy, particularly for patients with impaired renal function.

Drug Interactions. In elderly patients concurrently receiving certain diuretics, primarily thiazides, an increased incidence of thrombocytopenia with purpura has been reported. Bactrim may prolong the prothrombin time in patients who are receiving the anticoagulant warfarin. Keep this in mind when Bactrim is given to patients already on anticoagulant therapy and reassess coagulation time. Bactrim may inhibit the hepatic metabolism of phenytoin. Given at a common clinical dosage, it increased the phenytoin half-life by 39% and decreased the phenytoin metabolic clearance rate by 27%. When giving these drugs concurrently, be alert for possible excessive phenytoin effect. Sulfonamides can displace methotrexate from plasma protein binding sites, thus increasing free methotrexate concentrations.

Drug/Laboratory Test Interactions. Bactrim, specifically the trimethoprim component, can interfere with a serum methotrexate assay as determined by the competitive binding protein technique (CBPA) when a bacterial dihydrofolate reductase is used as the binding protein. No interference occurs if methotrexate is measured by a radioimmunoassay (RIA). The presence of trimethoprim and sulfamethoxazole may also interfere with the Jaffe alkaline picrate reaction assay for creatinine, resulting in overestimations of about 10% in the range of normal values.

Carcinogenesis, Mutagenesis, Impairment of Fertility. Carcinogenesis: Long-term studies in animals to evaluate carcinogenic potential not conducted with Bactrim. Mutagenesis: Bacterial mutagenic studies not performed with sulfamethoxazole and trimethoprim in combination. Trimethoprim demonstrated to be nonmutagenic in the Ames assay. No chromosomal damage observed in human leukocytes *in vitro* with sulfamethoxazole and trimethoprim alone or in combination; concentrations used exceeded blood levels of these compounds following therapy with Bactrim. Observations of leukocytes obtained from patients treated with Bactrim revealed no chromosomal abnormalities. Impairment of Fertility: No adverse effects on fertility or general reproductive performance observed in rats given oral dosages as high as 70 mg/kg/day trimethoprim plus 350 mg/kg/day sulfamethoxazole.

Pregnancy. Teratogenic Effects: Pregnancy Category C. Trimethoprim and sulfamethoxazole may interfere with folate acid metabolism, use during pregnancy only if potential benefit justifies potential risk to fetus. Nonteratogenic Effects: See CONTRAINDICATIONS section.

Nursing Mothers. See CONTRAINDICATIONS section.

Pediatric Use. Not recommended for infants under two months (see INDICATIONS and CONTRAINDICATIONS sections).

ADVERSE REACTIONS: Most common are gastrointestinal disturbances (nausea, vomiting, anorexia) and allergic skin reactions (such as rash and urticaria). **FATALITIES ASSOCIATED WITH THE ADMINISTRATION OF SULFONAMIDES, ALTHOUGH RARE, HAVE OCCURRED DUE TO SEVERE REACTIONS, INCLUDING STEVENS-JOHNSON SYNDROME, TOXIC EPIDERMAL NECROLYSIS, FULMINANT HEPATIC NECROSIS, AGRANULOCYTOSIS, APLASTIC ANEMIA AND OTHER BLOOD DYSCRASIAS (SEE WARNINGS SECTION).**

Hematologic: Agranulocytosis, aplastic anemia, thrombocytopenia, leukopenia, neutropenia, hemolytic anemia, megaloblastic anemia, hypoprothrombinemia, methemoglobinemia, eosinophilia. **Allergic Reactions:** Stevens-Johnson syndrome, toxic epidermal necrolysis, anaphylaxis, allergic myocarditis, erythema multiforme, exfoliative dermatitis, angioedema, drug fever, chills, Henoch-Schoenlein purpura, serum sickness-like syndrome, generalized allergic reactions, generalized skin eruptions, photosensitivity, conjunctival and scleral injection, pruritus, urticaria and rash. **Periarthritis nodosa** and systemic lupus erythematosus have been reported. **Gastrointestinal:** Hepatitis (including cholestatic jaundice and hepatic necrosis), elevation of serum transaminase and bilirubin, pseudomembranous enterocolitis, pancreatitis, stomatitis, glossitis, nausea, emesis, abdominal pain, diarrhea, anorexia. **Genitourinary:** Renal failure, interstitial nephritis, BUN and serum creatinine elevation, toxic nephrosis with oliguria and anuria, crystalluria. **Neurologic:** Aseptic meningitis, convulsions, peripheral neuritis, ataxia, vertigo, tinnitus, headache. **Psychiatric:** Hallucinations, depression, apathy, nervousness. **Endocrine:** Sulfonamides bear certain chemical similarities to some goitrogens, diuretics (acetazolamide and the thiazides) and oral hypoglycemic agents; cross-sensitivity may exist. Diuresis and hypoglycemia have occurred rarely in patients receiving sulfonamides. **Musculoskeletal:** Arthralgia, myalgia. **Miscellaneous:** Weakness, fatigue, insomnia.

DOSAGE AND ADMINISTRATION: Not recommended for use in infants less than two months of age.

URINARY TRACT INFECTIONS AND SHIGELLOSI IN ADULTS AND CHILDREN, AND ACUTE OTITIS MEDIA IN CHILDREN. Usual adult dosage for urinary tract infections is one DS tablet, two tablets or four teaspoonfuls (20 ml) b.i.d. for 10 to 14 days. Use identical daily dosage for 5 days for shigellosis. Recommended dosage for children with urinary tract infections or acute otitis media is 8 mg/kg trimethoprim and 40 mg/kg sulfamethoxazole per 24 hours, in two divided doses every 12 hours for 10 days. Use identical daily dosage for 5 days for shigellosis. **Renal Impaired:** Creatinine clearance above 30 ml/min, give usual dosage, 15-30 ml/min, give one-half the usual regimen, below 15 ml/min, use not recommended.

ACUTE EXACERBATIONS OF CHRONIC BRONCHITIS IN ADULTS. Usual adult dosage is one DS tablet, two tablets or four teasp. (20 ml) b.i.d. for 14 days.

PNEUMOCYSTIS CARINII PNEUMONITIS: Recommended dosage is 20 mg/kg trimethoprim and 100 mg/kg sulfamethoxazole per 24 hours in equal doses every 6 hours for 14 days. See complete product information for suggested children's dosage table.

HOW SUPPLIED: DS (double strength) Tablets (160 mg trimethoprim and 800 mg sulfamethoxazole)—bottles of 100, 250 and 500. Tel-E-Dose® packages of 100, Prescription Paks of 20 Tablets (80 mg trimethoprim and 400 mg sulfamethoxazole)—bottles of 100 and 500. Tel-E-Dose® packages of 100; Prescription Paks of 40. **Pediatric Suspension** (40 mg trimethoprim and 200 mg sulfamethoxazole per teasp.)—bottles of 100 ml and 16 oz (1 pint). **Suspension** (40 mg trimethoprim and 200 mg sulfamethoxazole per teasp.)—bottles of 16 oz (1 pint).

STORE TABLETS AT 15°-30°C (59°-86°F) IN A DRY PLACE PROTECTED FROM LIGHT. STORE SUSPENSIONS AT 15°-30°C (59°-86°F) PROTECTED FROM LIGHT.

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Action: Yohimbine blocks presynaptic alpha-2 adrenergic receptors. Its action on peripheral blood vessels resembles that of reserpine, though it is weaker and of short duration. Yohimbine's peripheral autonomic nervous system effect is to increase parasympathetic (cholinergic) and decrease sympathetic (adrenergic) activity. It is to be noted that in male sexual performance, erection is linked to cholinergic activity and to alpha-2 adrenergic blockade which may theoretically result in increased penile inflow, decreased penile outflow or both.

Yohimbine exerts a stimulating action on the mood and may increase anxiety. Such actions have not been adequately studied or related to dosage although they appear to require high doses of the drug. Yohimbine has a mild anti-diuretic action, probably via stimulation of hypothalamic centers and release of posterior pituitary hormone.

Reportedly, Yohimbine exerts no significant influence on cardiac stimulation and other effects mediated by B-adrenergic receptors; its effect on blood pressure, if any, would be to lower it; however no adequate studies are at hand to quantitate this effect in terms of Yohimbine dosage.

Indications: Yocon® is indicated as a sympatholytic and mydriatic. It may have activity as an aphrodisiac.

Contraindications: Renal diseases, and patient's sensitive to the drug. In view of the limited and inadequate information at hand, no precise tabulation can be offered of additional contraindications.

Warning: Generally, this drug is not proposed for use in females and certainly must not be used during pregnancy. Neither is this drug proposed for use in pediatric, geriatric or cardio-renal patients with gastric or duodenal ulcer history. Nor should it be used in conjunction with mood-modifying drugs such as antidepressants, or in psychiatric patients in general.

Adverse Reactions: Yohimbine readily penetrates the (CNS) and produces a complex pattern of responses in lower doses than required to produce peripheral a-adrenergic blockade. These include, anti-diuresis, a general picture of central excitation including elevation of blood pressure and heart rate, increased motor activity, irritability and tremor. Sweating, nausea and vomiting are common after parenteral administration of the drug.^{1,2} Also dizziness, headache, skin flushing reported when used orally.^{1,3}

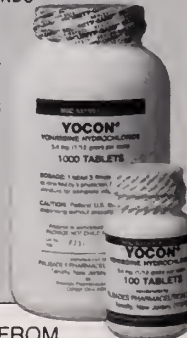
Dosage and Administration: Experimental dosage reported in treatment of erectile impotence.^{1,3,4} 1 tablet (5.4 mg) 3 times a day, to adult males taken orally. Occasional side effects reported with this dosage are nausea, dizziness or nervousness. In the event of side effects dosage to be reduced to 1/2 tablet 3 times a day, followed by gradual increases to 1 tablet 3 times a day. Reported therapy not more than 10 weeks.³

How Supplied: Oral tablets of Yocon® 1/12 gr. 5.4 mg in bottles of 100's NDC 53159-001-01 and 1000's NDC 53159-001-10.

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neck cancer; (2) recurrences on the chest wall in and around the mastectomy scar following surgery for cancer of the breast; and, (3) other superficially recurrent carcinomas, sarcomas and melanomas. In addition, many institutions participate in clinical investigations in which other potentially useful applications of hyperthermia are being studied, such as combining hyperthermia with the initial course of conventional radiation therapy to increase response rates. These approaches show considerable promise in clinical situations characterized by relatively high local failure rates following conventional therapy alone.

Future Directions

Research is currently directed toward improving the technology for heat delivery, particularly for deep seated tumors, to achieve preferential heating of tumor versus normal tissue. More accurate and less invasive thermometry, and development of the concept of "thermal dose" are needed. Clinical studies are underway in a number of centers to better define the role of hyperthermia for those conditions in which improved local control would result in cure or improved symptom-free survival. Further exploration of the potential for combined hyperthermia and chemotherapy is needed, as well as assessment of the long term sequelae of combined therapy. These and other recommendations have recently been summarized.⁴⁹ Progress in these efforts should further clarify the future role of hyperthermia in cancer therapy. □

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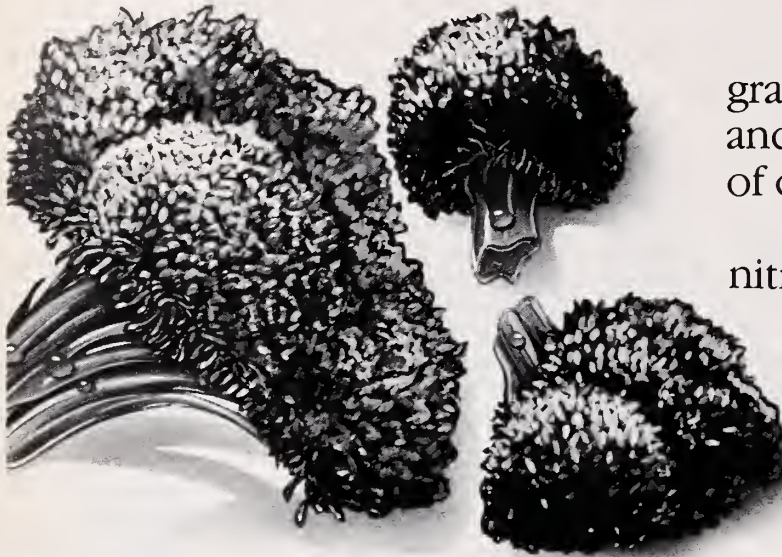
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Adolescent Health

Adolescence is defined as the developmental period between childhood and adulthood which is characterized by physical, sexual and psychological maturation. Once viewed as “fun and carefree” days, the teen years have become increasingly troublesome and dangerous.

Substance abuse among teenagers has become a major national issue. Teens are frequent objects of victimization through physical and sexual abuse; suicide and other psychological disorders have become pandemic; while physical problems continue to contribute to premature morbidity and mortality. Violence has become an increasingly pervasive element in society, even as part of entertainment — the average child is estimated to view 18,000 murders and countless acts of carnage on television before the age of 18.

No socioeconomic or racial group is entirely immune from these troubles but poverty is a primary factor. Poor teens risk the direct physical consequences of deprivation, severe stress on parent-child relationship, and the probability of a depreciated status in the social environment.

Even though poverty is a powerful factor in damage to children and adolescents, adequate income and high social status do not guarantee healthy growth and development. It appears to sociologists and educators that

among middle-class teens, values are shifting away from family. “More and more kids today are looking for some form of structure in their lives,” says one family psychologist. “The malls are a place they find it.”

For many teens, the result is a muddling of traditional middle-class values. In the places where they hang out, it’s not hard to find evidence of why many specialists are now saying that today’s teens are more materialistic, less realistic and harder to motivate than any generation before them.

Sociologists also worry that malls help create the illusion for kids that they already have it all, too. Under one roof, malls showcase all the easy-life images and conspicuous consumption seen on television. Only two generations removed from the Depression, today’s middle-class youth know little about poverty or the potential for it.

As our youth, as birds in flights from the nest, try out their wings many are not leaving a nest feathered with positive, nurturing attributes. Many nests are ridden with holes of divorce, poverty, lack of moral values and mothers working outside the home.

Coupled with declining family support is the statement made recently by University of Texas political scientist W. Norton Grubb, “Americans, also, have

never accepted much responsibility for other people's children. Kids are considered a parental responsibility."

Is it not understandable that the youth today are especially vulnerable to rising numbers of problems? A normal characteristic of adolescence is experimental behavior leading the way to potential danger both physically and psychologically.

It is during adolescence that some persons adopt self-damaging behaviors that can threaten or shorten life. Such behaviors include poor health practices; alienation from school and family; early and unprotected sexual intercourse; use of alcohol, illicit drugs and tobacco; delinquent and violent behavior and reckless and injury-prone behavior.

Despite all the identified hazards of their transitional stage in life, persons in this age group do not use physician services as frequently as do other population groups, in fact recent government data show that adolescents have the lowest rate of physician office visits of any age group.

Substance abuse among adolescents increased explosively in the 1960s and 1970s. While some forms of drug use have leveled off since then, alcohol and drug experimentation remain prevalent in this population group.

Alcohol is, by far, the abused more often and to a greater extent among males. Drinking adolescents are responsible not only for a large proportion of highway crashes and fatalities, but also for many cases of violent crimes and suicides.

About two-thirds of high school seniors have some experience with an illicit drug. Cocaine abuse clearly is on the rise. Accompanying — and partially explaining — this upswing has been the introduction of "crack," an inexpensive, potent and easily administered form of the drug.

While daily cigarette use by high school seniors dropped, the reduction in male smokers has been greater than in female smokers. There has been a recent trend, among males, toward use of smokeless tobacco products.

While statistics on sexual behavior do not summarize adolescent sexuality, they do confirm that many adolescents initiate sexual activity during a developmental stage characterized by risk-taking behavior and propensity to act without full sense of the potential consequences of their actions.

Alabama has one of the highest percentages of births to teens in the nation — greatly exceeding the national average. Alabama teenagers, also, have an alarmingly high number of repeat births. About 50% of teen mothers are on public assistance and are more likely to neglect and/or abuse their children. The risk of a baby dying in the first year of life increases as the age of the mother decreases below 20 years.

Much attention has been paid to the abuse of chil-

dren, but relatively little is known about maltreatment of adolescents. Twenty-four percent of all fatalities and forty-one percent of all serious injuries in reported cases of physical abuse involve persons aged 12 to 17. Half of all rape victims are less than 18 years old.

Among American adolescents between 13 and 18 years of age, 15% are sufficiently emotionally disturbed to require some form of helpful intervention. Five thousand persons under age 19 commit suicide each year and another 50,000 attempt suicide annually. One Alabama county reported 13 suicidal attempts by teens within three weeks. Two others were successful. A history of suicide in the person's community or family, a lack of problem-solving skills and substance abuse play a large role in this tragic problem.

Violence has become an increasingly prevalent element in modern society and adolescents are responsible for a third of all violent crimes.

One person or group of people such as MASA or its auxiliary can make a difference by addressing at least one negative aspect of adolescence, planning a strategy, equipping its membership with information and confronting young people at their most populated area-schools. Poignant posters, information flyers, testimonial style videos of other adolescents who have progressed through the problems could have a tremendous impact.

Adolescent health has always been a major focus of auxiliary activities, but auxiliaries are now being asked to step up these efforts by joining the AMA in its Initiative on Adolescent Health, which is an ongoing, comprehensive plan for helping teens grow into healthy adults.

"The AMA White Paper on Adolescent Health" a resource for much of this article, may be obtained by contacting: The Clearinghouse on Adolescent Health, AMA, 535 N. Dearborn St., Chicago, IL 60610; (312) 645-4545. □

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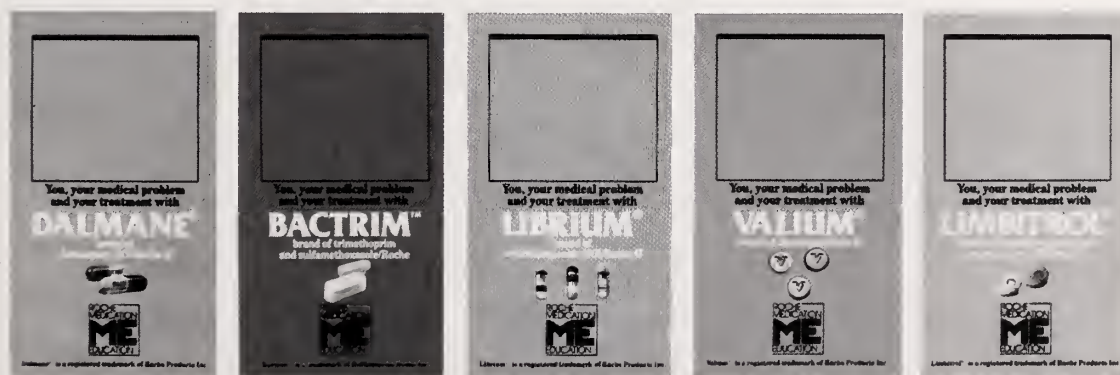


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Cover

William A. Leitner, M.D. takes office as the 1988-89 President of MASA at annual session this month in Montgomery. Dr. Leitner has adopted as one of the themes of his presidential year a return to patient-oriented care, perceived by many physicians to have been eroded by marketplace changes. While physicians may no longer have the clout they once had with third-party payors, Dr. Leitner believes the nation's millions of patients still look to their doctor for health care, not an impersonal delivery system of whatever configuration. Therein lies the multiplier effect of the American physician's political strength, Dr. Leitner believes.

Back to the Fork in the Road

William H. McDonald

There was a time, ending four or five decades ago perhaps, when a farm-family background for a physician was more the rule than the exception. At the most, the average young physician of the 20s and 30s was but a generation removed from the soil.

Today, in medicine as in all callings, the farm background is rare and getting rarer with every passing day. And the Republic may be the poorer because of it. Although farm life has been romanticized beyond recognition by some latter-day exponents of back-to-the-land movements, there is no gainsaying the fact that a childhood amid the fields and furrows inculcated a sense of place, self-reliance, and an abiding humanity that has no metropolitan equivalent. More's the pity.

William A. Leitner, M.D., MASA's President for 1988-1989 is one of those rarities. He spent his early years on his family dairy, tobacco and cotton farm at Marion, South Carolina, where the tallest building was a silo. It is entirely possible that he will be the last MASA President so reared.

In his spanking new offices behind Birmingham's St. Vincent Hospital, Dr. Leitner seems as far removed from cows and cotton as a man could be, but his background shows on occasion.

It shows in his expressed belief that in these times of marketplace turbulence (a condition not unknown to farmers) the central message is simplicity itself: Physicians, distracted the past few years by all manner

of economic turmoil and change, must rededicate themselves to patient-oriented care.

It will be one of Dr. Leitner's themes as President to persuade physicians that: although they have less influence with third-parties than they once did; although their clout in Washington has been diminished by the rise of competing influences such as AARP, no one has more influence than their patients who, collectively, will determine the future of American health care.

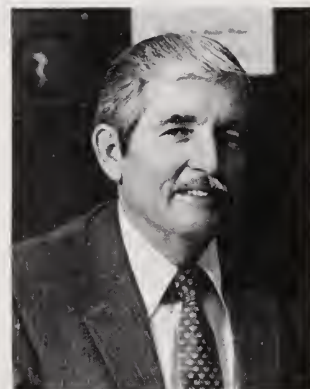
While Americans are generally suspicious of bigness in anything, whether big labor, big business, big government or big professional associations, the individual doctor's stock with his patients remains largely unaffected by the winds of change. Poll after poll has shown that while Americans are leery of organized medicine as a group, they remain convinced that *their* doctor is an exception.

Multiply these "exceptions" by the millions of patient contacts every year and you have basically the U.S. population. That is where medicine's strength lies, Dr. Leitner believes, in the one-on-one relationships to the 6th power or more.

"Physicians should get back to concentrating on patient care, with all that implies," he says. "Spend more time with patients, learn what their concerns are other than the illness they may have. In other words,

continued on page 12

EXECUTIVE DIRECTOR



*S. Lon Conner
Executive Director, MASA*

The Most Precious Coin

Few members of the Association realize how much time and energy their officers devote to the welfare of the membership. The two-day monthly meetings in Montgomery are only the start of it.

Throughout the month they are constantly bombarded with reams of paper on an infinite variety of subjects, letters, and frequent calls, individual and conference.

This is a considerable sacrifice in that most precious of doctor commodities, time. That they cheerfully perform all these duties year in and year out has never ceased to amaze me in the years I have been your executive director (now going on 12 years).

Carl A. Grote, Jr., M.D., your President for the past year, is a good example. Dr. Grote has made many trips from Huntsville to Montgomery for monthly meetings and other conferences in between. He has traveled considerably, in-state and out-of-state, during that time.

A President actually serves for three years: as President-elect; as President; and as Immediate Past President — thus assuring continuity of care in the office.

At the annual meeting this month in Montgomery, Dr. Grote will put down the burdens of the presidency, but will serve another year on the Board of Censors.

I know I speak for the Board and undoubtedly for the membership when I express the appreciation of all for his year of sterling achievement and dedication. Dr. Grote is the plain-spoken and worthy son of a pioneering public health officer, Carl A. Grote, Sr., M.D. He has reflected glory on himself and his late father in his service to MASA, including prior service as Censor and as Board Chairman.

Thank you, Dr. Grote. Well done, sir.

His shoes will be ably filled by William A. Leitner, M.D., Birmingham. Dr. Leitner also brings to the office prior service on the Board, many years in other notable contributions to organized medicine, at county

and state levels. He has served as President of the Jefferson County Medical Society and on various committees. He has been involved in AlaPAC for a number of years, and is currently chairman of that vitally important function. He is also an AMA delegate.

Dr. Leitner's route to his present position was novel. Born on a South Carolina farm in the midst of the Great Depression, he graduated from college with a degree in chemical engineering and had done graduate work at Georgia Tech before getting the call to medicine. Some credit for that switch must go to the Army, in a negative way. (See Bill McDonald's profile on Dr. Leitner in this issue.)

Drs. Leitner and Grote and all your officers reverse the usual idea of work. Instead of being paid for their Association work, they pay for the privilege of doing it. They pay in the most valuable coin of the realm in medicine, time.

Doctors have less of that than almost any group in the land (as you have known all along and as I quickly found out). Scarcity creates value. If the government of the U.S. ever adopts a Value Added Tax (VAT, popular in Europe) on services as well as goods, I have no idea how your officers' time contributions to the Association would be computed. But I am thankful that this is a non-profit organization.

Much of physician time is what the efficiency experts call "inelastic time" — time that has already been stretched to the limit of its elasticity, or time that cannot be stretched at all. The classic example of inelastic time is gestation: producing a baby cannot be made more efficient by delegating or dividing the work. Not even the in vitro fertilization folks have figured out a way to produce a baby by assigning nine women the job and giving each one month to do it. (Curiously, something just as idiotic is being asked of doctors by many third-party payors, public and private, in their insistence that physicians have all the time in the world for more and more paperwork, red tape, cost-over-care priorities, and other mindless impositions on precious time.)

Some of the time your officers divert to your affairs

may come from practice, which often means that a partner covers and thus also serves. But most of it comes from their private time, already at a virtually irreducible minimum.

I don't know how they do it. But after more than 11 years of observing this dedication I think I know *why* they do it. They do it not out of a sense of sacrifice but of conviction that they are not contributing but repaying a debt — the debt all physicians (whether they acknowledge it or not) owe their profession; a debt assumed when they entered medicine; a debt owed to the physicians who went before and those to follow.

It is a singular conviction. Nothing in my previous life had prepared me for this phenomenon. And nothing in my medical association experience has yet prepared me to excuse those physicians who don't have it, who can't be bothered.

Every occupation and profession has its freeloaders, I know, but in medicine's grand tradition of selfless dedication they certainly stand out more. There is a curious added dimension to the personality of the "let-George-do-it" physician: very often he is the one who complains the loudest, even threatening to disassociate himself from organized medicine, when the profession suffers setbacks and defeats, as it has always has and always will.

If the day ever comes when the number jeering on the sidelines exceeds those on the playing fields of organized medicine, the profession, as you have known it, is finished.

In Massachusetts, physicians supported their association with nowhere near the total effort in Alabama. They were subjugated as a result. I can see no present danger of comparable dereliction in this state, but if it happens the consequences will be similar. ◻

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CODEINE	X	X	X	X	X
OXYCODONE	XX	XX	XX	XX	XX

Blank space indicates that no such activity has been reported.

Table adapted from Facts and Comparisons (Nov.) 1984 and Catalano RB. The medical approach to management of pain caused by cancer. "Semin Oncol" 1975; 2; 379-92 and Reuler JB, et. al. The chronic pain syndrome: misconceptions and management. "Ann Intern Med" 1980; 93; 588-96.

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PRECAUTIONS:

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Information for Patients: VICODIN, like all narcotics, may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery; patients should be cautioned accordingly.

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Drug Interactions: The CNS-depressant effects of VICODIN may be additive with that of other CNS depressants. When combined therapy is contemplated, the dose of one or both agents should be reduced. The use of MAO inhibitors or tricyclic antidepressants with hydrocodone preparations may increase the effect of either the antidepressant or hydrocodone. The concurrent use of anticholinergics with hydrocodone may produce paralytic ileus.

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Revised, April 1982.

S685

1. Hopkinson JH III: *Curr Ther Res* 24: 503-516, 1978
2. Beaver, WT *Arch Intern Med*, 141:293-300, 1981.

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PRESIDENT'S PAGE



Carl A. Grote, Jr., M.D.
President, MASA

Thanks For Everything

It is hard for me to realize that twelve months have gone by so quickly and that this will be my last column.

The preparation of this column is one of the things that I looked forward to with a certain amount of anxiety as I came into office last April. However, with the help of able staff in Montgomery, it has been rendered almost painless.

In fact, I would have to say that the preparation of the President's column has been a very rewarding experience. I have been delighted to find out how many people read *Alabama Medicine* in particular this column. Rarely does a month go by that I don't get some type of feedback from the column. It has served as not only a way for me to express my views on certain topics but to find out the feeling of the membership on these topics. Letters, telephone calls and many personal contacts have let me know what is on your mind and made me better able to represent you in many arenas.

Several of the columns have had to do with my frustrations in dealing with third parties in the day-to-

day practice of medicine. I hope that I have not come across in too negative a fashion. In spite of all of my frustrations, I still think that we have one of the greatest professions of all and I wouldn't swap my M.D. degree for anything else that I can think of.

I often have an opportunity to interview prospective medical students. One of the questions that I am frequently asked by these young people is, "Would you do it all over again?" My answer is always a resounding "Yes."

A few weeks ago I was walking from the parking garage to the hospital with one of my younger colleagues. He had just read one of my columns and made a few comments. As we walked on a little further he said, "Carl, my son says he wants to go to medical school, what do you think I ought to do?" "Encourage him," I said. He responded, "You've got to be kidding." "Absolutely not," I said, "just stop and think for a minute. I've known you for a number of years and I know that you enjoy what you do. How many people do you know who get to spend their lives doing the things they really like to do. Also, we make a

pretty good living.” He stopped and thought for a few minutes and said, “Well, I guess you’re right.”

In recent months it has come to my attention that we are having fewer applicants to medical school than we have in a long period of time. Also, the caliber of student has fallen somewhat from what it has been. It is becoming evident that fewer and fewer people who are going into medicine are going into primary care.

While the oversupply of physicians continues to be of concern in most quarters, there will always be room for bright young people in medicine. We should encourage these people rather than discourage them.

One of the lessons that I learned early from my father was the joy of practicing medicine. There was never a day when he did not look forward to going to work. When asked what his hobby was, he would give one or two answers: practicing medicine or Huntsville Hospital. One of the more fortunate things in his life was that he was able to practice right up until the time of his death. If you have never known anyone who has loved to practice medicine in that way, then you have missed something in your own life.

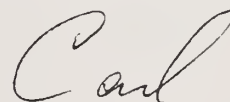
So maybe we have to bear a lot of the blame for the decrease in the number of bright young people applying to medical school in this day and age. Maybe we are too much the forecasters of gloom and doom and should look more on the positive side of our profession rather than presenting a negative outlook. Our generation has the responsibility to see that bright young

people continue to apply to medical school and fill the ranks of those with M.D. after their name.

If in years to come the practice of medicine isn’t what it should be, then it is we who have to bear the blame. The medical profession has had in the past, and will have in the future, a great opportunity to shape its own direction. An example of what can be accomplished when doctors unite in a common cause is the passage of tort reform last year. An example of what can be lost when they do *not* participate is the Massachusetts Mandatory Assignment for Licensure and the small percentage there participating in their Medical Association and state PAC movement.

If we do not like some of the things that have happened to medicine in recent years, we must bear some of the responsibility. Those that went before us left us a legacy of the finest medical delivery system in the world. We have an obligation to those that come after us to see that it remains such and that medicine remains the finest profession that will attract bright young people of the future.

This year has been an honor and a pleasure. I hope that I have been worthy of the confidence that has been placed in me. □



Fork in the Road

continued from page 4



we must all get back to what we should have been concentrating on all along — the patient comes first, above everything.

“There has been an understandable tendency in recent years for us to become distracted by all the market commotion. In the process, we may have been enticed into making market concerns more pressing than patient concerns. This is wrong.

“It is wrong because our job is patient care. And it is wrong, from a selfish standpoint, because our influence is still strong with individual patients. We may not have the voice we once had in Washington; we may not have the influence we once had with carriers and with big business. But we remain strong in our individual relationships with patients.

“It’s not the government they turn to for care; not the insurance company, not the system — it’s their doctor, in whatever setting they find him. That relationship is our calling. It is also our salvation. In the final analysis, what patients think about any health care delivery system, from private practitioner to the huge prepaid plan, is determined by the patient’s regard, whether high or low, for the physician’s care.

“If we do our best at all times, the millions of American patients will fight our battles for us. They will determine what the political future holds for our profession. After all, patients are numbered in the tens of millions; doctors only in the hundreds of thousands. It follows that our clout nationally is a function of how well we serve those millions of patients who are the voters Congress must satisfy in the end.”

You will see in this, as in other of Dr. Leitner’s convictions, the unmistakable influence of the family farm: personal integrity; do it right the first time and every time; the fundamental importance of human relationships; and, above all perhaps, interest in and concern for people and their paramount worth as individuals. That is not an act; he means it.

William A. Leitner was born in the depression year of 1935. His father was then a sophomore at Clemson. When his father graduated, the Leitners moved back to the family farm at Marion, to dairying and growing

cotton and tobacco. Then his grandfather died in 1939, and his father the following year. The family farm was in jeopardy.

“My mother and grandmother tried to hold the farm together for four years, but it didn’t work out. We got out of farming during World War II.”

Shortly after the war his mother remarried; young Bill Leitner was fortunate. His stepfather was a good man, an agricultural engineer who headed the engineering department of the South Carolina Agricultural Extension Service.

“When I was a sophomore in high school, my stepfather, of who I am very fond, came to me and said: ‘Now look, with your birthday I want you to go to college next year so you will be a sophomore when you become eligible to go to Korea. I want you to be an officer if you can. . . .’

“So I finished high school a year early and went to Clemson a year early. I was interested in chemistry and he was an engineer. He thought chemical engineering would be a good field for me. He convinced me.”

After he received his degree in chemical engineering from Clemson, the Army called. He spent most of his two years of service in the legal office at Fort Benning, Columbus, Georgia.

As another example of the inscrutable wisdom of the Army in job placement, the young chemical engineer was designated a trial counsel. He spent 13 long months trying cases of AWOL and “that kind of mess” and holding hearings for alleged homosexuals. Those found guilty of the allegations were “boarded out of the service.”

It was not, as might be deduced, the most enlightening of times for Bill Leitner.

It would have been the most dismal of times for the young chemical engineer except for the serendipitous discovery of his future bride, the lovely Dena Wetherbee, lately of Camden, Alabama. She was teaching in the Columbus school system.

His two years completed, he opted for graduate work at Georgia Tech, that institution chosen less for its



continued on page 15

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Warnings: Do not use potassium supplements, dietary or otherwise, unless hypokalemia develops or dietary intake of potassium is markedly impaired. If supplementary potassium is needed, potassium tablets should not be used. Hyperkalemia can occur, and has been associated with cardiac irregularities. It is more likely in the severely ill, with urine volume less than one liter/day, the elderly and diabetics with suspected or confirmed renal insufficiency. Periodically, serum K⁺ levels should be determined. If hyperkalemia develops, substitute a thiazide alone, restrict K⁺ intake. Associated widened QRS complex or arrhythmia requires prompt additional therapy. Thiazides cross the placental barrier and appear in cord blood. Use in pregnancy requires weighing anticipated benefits against possible hazards, including fetal or neonatal jaundice, thrombocytopenia, other adverse reactions seen in adults. Thiazides appear and triamterene may appear in breast milk. If their use is essential, the patient should stop nursing. Adequate information on use in children is not available. Sensitivity reactions may occur in patients with or

without a history of allergy or bronchial asthma. Possible exacerbation or activation of systemic lupus erythematosus has been reported with thiazide diuretics.

Precautions: The bioavailability of the hydrochlorothiazide component of 'Dyazide' is about 50% of the bioavailability of the single entity. Theoretically, a patient transferred from the single entities of triamterene and hydrochlorothiazide may show an increase in blood pressure or fluid retention. Similarly, it is also possible that the lesser hydrochlorothiazide bioavailability could lead to increased serum potassium levels. However, extensive clinical experience with 'Dyazide' suggests that these conditions have not been commonly observed in clinical practice. Angiotensin-converting enzyme (ACE) inhibitors can elevate serum potassium; use with caution with 'Dyazide'. Do periodic serum electrolyte determinations (particularly important in patients vomiting excessively or receiving parenteral fluids, and during concurrent use with amphotericin B or corticosteroids or corticotropin [ACTH]). Periodic BUN and serum creatinine determinations should be made, especially in the elderly, diabetics or those with suspected or confirmed renal insufficiency.

Cumulative effects of the drug may develop in patients with impaired renal function. Thiazides should be used with caution in patients with impaired hepatic function. They can precipitate coma in patients with severe liver disease. Observe regularly for possible blood dyscrasias, liver damage, other idiosyncratic reactions. Blood dyscrasias have been reported in patients receiving triamterene, and leukopenia, thrombocytopenia, agranulocytosis, and aplastic and hemolytic anemia have been reported with thiazides. Thiazides may cause manifestation of latent diabetes mellitus. The effects of oral anticoagulants may be decreased when used concurrently with hydrochlorothiazide; dosage adjustments may be necessary. Clinically insignificant reductions in arterial responsiveness to norepinephrine have been reported. Thiazides have also been shown to increase the paralyzing effect of nondepolarizing muscle relaxants such as tubocurarine. Triamterene is a weak folic acid antagonist. Do periodic blood studies in cirrhotics with splenomegaly. Antihypertensive effects may be enhanced in post-sympathectomy patients. Use cautiously in surgical patients. Triamterene has been found in renal stones in association with the other usual calculus components. Therefore, 'Dyazide' should be used with caution in patients with histories of stone formation. A few occurrences of acute renal failure have been reported in patients on 'Dyazide' when treated with indomethacin. Therefore, caution is advised in administering nonsteroidal anti-inflammatory agents with 'Dyazide'. The

following may occur: transient elevated BUN or creatinine or both, hyperglycemia and glycosuria (diabetic insulin requirements may be altered), hyperuricemia and gout, digitalis intoxication (in hypokalemia), decreasing alkali reserve with possible metabolic acidosis. 'Dyazide' interferes with fluorescent measurement of quinidine. Hypokalemia is uncommon with 'Dyazide', but should it develop, corrective measures should be taken such as potassium supplementation or increased dietary intake of potassium-rich foods. Corrective measures should be instituted cautiously and serum potassium levels determined. Discontinue corrective measures and 'Dyazide' should laboratory values reveal elevated serum potassium. Chloride deficit may occur as well as dilutional hyponatremia. Concurrent use with chlorpropamide may increase the risk of severe hyponatremia. Serum PBI levels may decrease without signs of thyroid disturbance. Calcium excretion is decreased by thiazides. 'Dyazide' should be withdrawn before conducting tests for parathyroid function. Thiazides may add to or potentiate the action of other antihypertensive drugs. Diuretics reduce renal clearance of lithium and increase the risk of lithium toxicity.

Adverse Reactions: Muscle cramps, weakness, dizziness, headache, dry mouth; anaphylaxis, rash, urticaria, photosensitivity, purpura, other dermatological conditions; nausea and vomiting, diarrhea, constipation, other gastrointestinal disturbances; postural hypotension (may be aggravated by alcohol, barbiturates, or narcotics). Necrotizing vasculitis, paresthesias, icterus, pancreatitis, xanthopsia and respiratory distress including pneumonitis and pulmonary edema, transient blurred vision, sialadenitis, and vertigo have occurred with thiazides alone. Triamterene has been found in renal stones in association with other usual calculus components. Rare incidents of acute interstitial nephritis have been reported. Impotence has been reported in a few patients on 'Dyazide', although a causal relationship has not been established.

Supplied: 'Dyazide' is supplied as a red and white capsule, in bottles of 1000 capsules; Single Unit Packages (unit-dose) of 100 (intended for institutional use only); in Patient-Pak™ unit-of-use bottles of 100.

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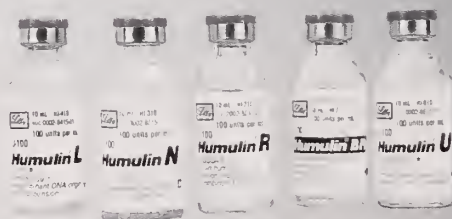
The clinical significance of insulin antibodies in the complications of diabetes is uncertain at this time. However, high antibody titers have been shown to decrease the small amounts of endogenous insulin secretion some insulin users still have. The lower immunogenicity of Humulin has been shown to result in lower insulin antibody titers; thus, Humulin may help to prolong endogenous insulin production in some patients.

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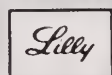
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Fork in the Road

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reputation in engineering than for its proximity to Columbus, Dr. Leitner admits today.

But Army life and the discovery of the love of his life had somehow changed his attitude toward chemical engineering. It no longer seemed enough.

"It became more and more obvious to me that I was not cut out for engineering. It seemed too far from the action to the results. It was then I turned to medicine because I wanted to do something 'more worthwhile.'" He and Dena were married in 1959.

He already had all his requisite pre-med studies but biology, which he took at Georgia Tech. After two years, he found himself in the class of 1964 at the Medical College of Alabama. Dena taught school at Mountain Brook, and here began a remarkable chain of circumstances that profoundly influenced their future:

One of her star pupils of pupils was Sam Cohn, son of Samuel K. Cohn, M.D., Birmingham urologist. Dena's father was a patient of Dr. Cohn's. (Sam Cohn, Jr., Ph.D., is now a noted professor at Brandeis, one of the two or three people in the world specializing in computer applications to ancient art and manuscripts.)

Also while in med school, Dr. Leitner externed at St. Vincent's. (All these loose strands were to come together in 1972, when Dr. Leitner joined Dr. Cohn's urology group.)

Fourth in his graduating class, young Dr. Leitner had been accepted for a residency at Johns Hopkins, but Hopkins directed that he go to Duke first. He and Dena found a home in Duke, which at the time was reputed to have a better urology program than did Hopkins. Dr. Leitner accordingly resigned his Hopkins residency and stayed on at Duke for the completion of his training.

While in Durham he met a Macon, Georgia, urologist, Ralph Newton, M.D., through a mutual friend, a Durham urologist. One thing led to another and, finishing at Duke, Dr. Leitner joined Dr. Newton in Macon.

It was not the happiest of times for the Leitners:

"I had more work than I could shake a stick at. There didn't seem to be any end of it. I worked every day, worked on my day off, came home late and left early. But I could have adjusted to that a lot better if I had access to an academic system, which I missed. I became increasingly annoyed because we had to send the big cases out, cases we could have handled had we had the facilities. Everyone was horribly overworked."

Because Dena had taught Dr. Cohn's son, and because Dr. Cohn was her father's doctor, Dr. Leitner inquired of the Birmingham urologist for advice on his next move. He was asking for advice, not a job,

but Dr. Cohn volunteered that his group would like to have him in a year although no vacancies then existed.

Dr. Leitner served out that year in Macon, and moved to Birmingham in 1972. Now in the Urology Associates group, he has recently moved into a new office at 2700 10th Avenue South, just behind St. Vincent's.

His first entry into organized medicine was as secretary-treasurer (later President) of the Medical School Alumni Association. He took it from its infancy, with perhaps 16 attending a meeting, to the now heavily attended Alumni Weekend, which has come to be an institution that has attracted 600 old grads.

In the late 70s, when the MASA representative to the Blue Cross board left that body, Dr. Leitner was persuaded by Derrill Crowe, M.D., and Ronald Henderson, M.D. (both then on the Board of Censors) to consider that job. He accepted the Board's appointment to the Blues board. In a short time, Dr. Henderson drafted Dr. Leitner for help in a Jefferson County fund-raising for Alapac. Then came a nomination to the Jefferson County Medical Society's Mediation and Medical Ethics Committee, on which he served for several years. That led to the vice presidency of the county society and then the presidency.

When Dr. Crowe decided to resign from the Board of Censors in late 1981, he asked Dr. Leitner if he would consider serving, if appointed, to the unexpired term. Again Dr. Leitner yielded to the influence of the famous Class of '62, which includes Drs. Crowe and Henderson, along with Drs. Kenneth C. Yohn, immediate past president of the Association, and Earle Riley, current Chairman of the Board of Censors.

Dr. Leitner is also an AMA Delegate.

Had Dr. Leitner not served his two years in the Army and done graduate work at Georgia Tech, he would have been in a class or two ahead of the famous movers and shakers of '62. Instead, he was two years behind and they became his mentors in organized medicine rather than he theirs.

Dr. Leitner was up for election (unopposed) to the Board of Censors when the medical staff at St. Vincent's decided it needed some input into the administration of the hospital. The staff's first choice for a medical director was unacceptable to the Administration. After some deliberations, Dr. Leitner emerged as the compromise candidate acceptable to both sides.

He took the job, which added a good 12 hours to his work week, but felt he was spreading himself pretty thin. Feeling he could not do justice to all the outside work he had taken on, he chose to step down from the Board of Censors.

A couple of years ago, after the St. Vincent job had settled into something approaching routine, the Class of '62 struck again.

At a breakfast meeting, Dr. Riley confided that after

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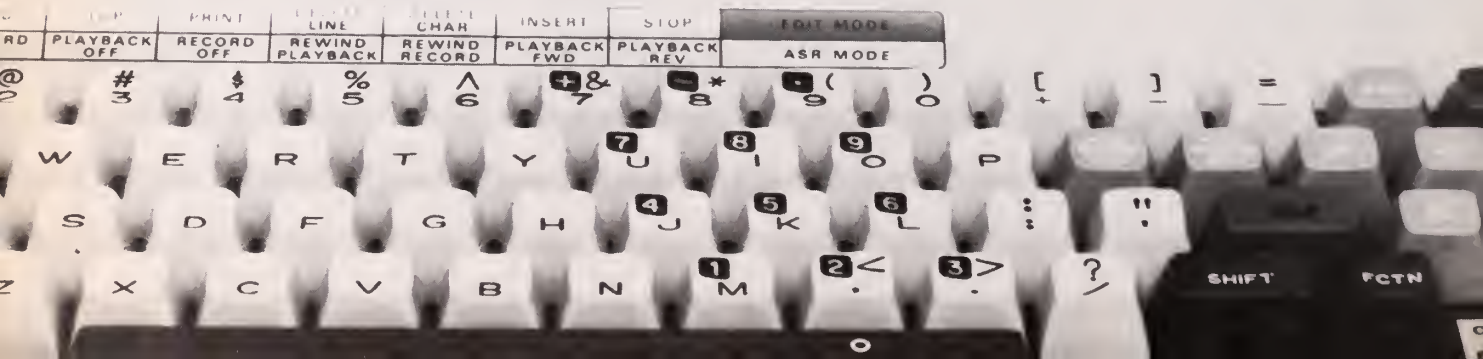
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Fork in the Road

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Carl C. Grote, Jr., M.D., there were no obvious candidates for presidency of the Association and would he consider a nomination? He would. This month he takes office at annual session in Montgomery.

The Leitners daughter Leigh, a Phi Beta Kappa graduate of the University of Virginia, is employed as an analyst with Morgan Stanley in New York City. Son Bill is a Junior at Washington & Lee who vows he plans to go to medical school. (Dr. Leitner: "If he is, he's taking a rather peculiar route. At the moment he is majoring in journalism and economics and will probably get his degree in economics. But he says he is going to get his pre-med out of the way at some point and study medicine. We'll see.")

As has been the custom in *Alabama Medicine* over the past several years, the incoming president is interviewed on his thoughts, plans, worries and hopes. The following exchange took place Feb. 29, 1988 in Birmingham:

Question: Apart from your many roles in organized medicine, you have had some rather extensive experience as medical staff liaison to hospital administration. What have you learned in that capacity?

Answer: "I've learned a lot about administration and a fair amount about running a hospital. I spent 12 hours a week at first in my role as medical director but now I spend about 6 hours. There are some really tough decisions. Sometimes the hospital must deny things that seem reasonable. I have learned that resources are finite. But it helps if there is a representative of the medical staff with his foot in administration. It helps to soften hard decisions and to at least make them more understandable."

Q: From our previous conversations, I gather that you intend to make one of the themes of your term as MASA President a "Back to Basics" advocacy. Would you elaborate?

A: "By that I mean that physicians need to rededicate themselves to patient-oriented care. I think we may have drifted from what should be our course, and was before all the recent disruptions blew us off it. I see no other way for the physician to recapture his influence and autonomy than to intensify his commitment to his patients.

"If all doctors do that in earnest, it would be a return to no more than what we should have been doing all along. It will also increase our influence, which is at low ebb, certainly in Washington. Rebuilding influence and clout, through millions of patient encounters, may strike some physicians as less than dramatic. But we don't have any other options, as I see it, no alternative to rebuilding brick-by-brick the influence we once had.

"That influence came, I believe, as the product of

millions of Americans being satisfied with their individual doctors. Maybe we have forgotten those origins of our esteem. Or maybe we have traded on them too long without replenishing the source.

"Whatever it is, if American patients are satisfied with medical care, they will fight our political battles for us. Congressmen may not be as attentive as they once were to the aspirations and concerns of a half-million or so physicians. But you can be sure they listen to the millions in the electorate, and they are our patients.

"Therein lies our strength. If we practice the best medicine we can, treat our patients with dignity and respect, try to help them with their insurance and other problems associated with their illness, show them we genuinely care, the dividends will be at least twofold: We will be doctors again rather than merchants or entrepreneurs. And we will have as our lobby millions upon millions of satisfied patients to form the national consensus that will determine the future of health care in this country.

"I am persuaded this is our only access, our only way to influence the system. What better lobby could we have than the whole American electorate?

"By back-to-basics I also mean big things and small things that we may have let slip in recent years. Physicians should, for example, spend more time on scheduling. Patients hate to wait. We all do. Of course some wait is often inevitable, but we can do more to minimize it.

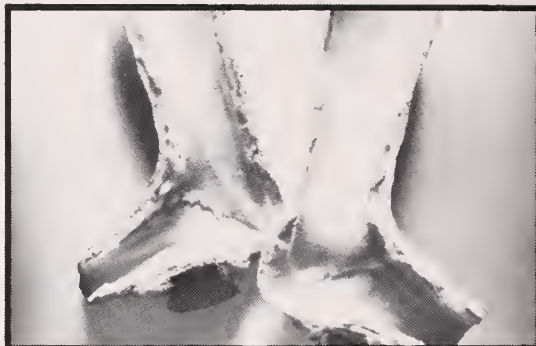
"A recent President of the Los Angeles County Medical Association put it well when he said that for the private practitioner marketing comes down to this: 'Find out what patients like and give them more of it. Find out what patients don't like and give them less.' It's that simple and I think most of us can find ways to improve delivery of services.

"What I am saying is that carriers do not listen to us. Their customers, those they have decided they must please, are those companies and institutions that buy from them. The government is not going to listen because it has other constraints. So the major buyers of health care, public or private, are thinking mainly of the bottom line. Cost, at least for now, is everything with them. But patients can only be pushed so far, and carriers know it. To a very real degree, we control what patients think. In the world of commerce, such an interface with the consumer is called 'point of sale advertising.' And it has significant effect on buyer attitudes and choices. In short, we can control public opinion, the final arbiter, far more than we may understand.

"Another basic I hope we can return to is physician involvement in community affairs. Nothing burnishes the public image of the doctor as a public-spirited

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Fork in the Road

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citizen better than our working shoulder-to-shoulder with other citizens on pressing community concerns. There was a time when the physician was expected to be one of the pillars of his community. I would like to see that time return.

"We also need to get involved with youngsters, encouraging bright and ambitious young people to consider medical science as a career. Jim Sammons has hammered away at this theme and we should pick up on it. Medical school applications are plummeting. Worse, some of the best students, for a variety of reasons, are turning away from medicine."

Q: In other words, your prescription for back to basics is quite complex?

A: "Yes it is, but only because the problem itself is complex. For too long, I believe, we have let slide considerations that were once obligatory to practice. To cite another facet: American women purchase two-thirds to three quarters of all health care — and may influence much of the rest. Obviously, then, organized medicine must be very attentive to what the American woman wants and expects.

"As wives and mothers, women have been quoted in polls as faulting American medicine for not paying more attention to prevention. For example, they cite our absence in the rediscovery of exercise, which has become a national phenomenon, touching almost everything. Are they right? They may well be. Why didn't we sponsor aerobics?"

Q: And what office protocols do you believe could be stressed to satisfy women?

A: "All the above, of course, but also including such good practice procedures as the follow-up — we call it our exit poll — to make sure you are delivering the product you think you are. Everyone appreciates the follow-up call, but women particularly. They are very value-conscious, as the market research folks will tell you. They also expect us to help guide them through the insurance maze, and that should be a part of our service freely and cheerfully provided."

Q: You are saying then that for the American physician to regain his autonomy and control he must earn it with the public?

A: "Precisely. We simply need to be a little bit better in some areas and a whole lot better in others, if we are to recapture the clout we had. The AMA is going four bells and a jingle on this right now: it has beefed up the Council of Scientific Affairs to the extent that the press is once again calling for the authoritative word on issues of the day. Great.

"We need to do something similar in our individual practices. We need to constantly ask ourselves: Am I indispensable to my patients? If we examine the evidence objectively and doubt that our answer is af-

firmative, we should get busy. We should be indispensable."

Q: Will all this assure the survival of private practice and fee-for-service medicine?"

A: "I certainly believe so. But Robert Naisbit in *Megatrends* was right in one of his themes. Americans do have more choices today than ever before. I expect to see younger Americans perhaps opting for an HMO kind of care while middle-aged and older will continue to favor more traditional settings. Right now, HMOs and similar prepaid mechanisms are in trouble because the big companies who pay the bills are squeezing the HMO dollar so tightly there's no profit left.

"But I would expect something like HMOs to be maybe a third of the market or less. And private practice itself is presently evolving toward the group — meaning three physicians or more. Some are saying that the optimum may be 15 in a group — just enough to afford a marketing budget and small enough to be run by one person.

"HMOs may have been oversold on the economy-of-scale theory. There are just so many things you can accomplish in an office to become more efficient, and those can be accomplished in an office of three physicians as well as in an office of 12 or 15. HMOs have been eaten up by administrative costs. And there may in fact be a practical limitation on size. By way of comparison, in other business and industry there is a definite trend away from bigness toward smaller operating units, which are seen as more efficient and more economical. The smaller operating unit defines most of private practice."

Q: What is the biggest problem facing organized medicine in the near term?

A: "I would like to answer that in parts. The biggest *internal* problem on the horizon is the controversy that may follow release of the Harvard-AMA relative value scale. If that scale, due out this summer, proposes some rather large reductions for certain specialties and procedures, it is going to be very difficult to hold organized medicine together and to prevent small groups from approaching legislative bodies to cut deals of their own. The relative value scale may expose the fact, or the allegation, that some specialties are not receiving their due while others may be receiving too much. Obviously, here you have the makings of a serious controversy which could be very divisive.

"The most emotional *external* problem right now here in Alabama is the liability situation. Our biggest responsibility is to make sure the tort reforms are not overturned by the courts. That means that the Supreme Court races are all important. Our goals should be to elect judges who are reasonable and fair, judges who will be guided by what is appropriate for the people."

Q: How would you rank these state races against,

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say, the election of the next President?

A: "For the self-interest of Alabama physicians I believe the make-up of the State's Supreme Court is more important than who the next President will be."

Q: But overall, encompassing all the above, you would say that the restoration of physician autonomy is the paramount concern?

A: "Without question, because all other problems fall under this rubric. What we are seeing, as every doctor knows, are administrative restrictions being placed on medicine by the payors of the bills and their customers who are buying the product. That, to my mind, is the biggest difficulty we have. And it is grave. It involves wrenching away the technical aspects of medicine from the hands of the person who has traditionally made the decisions — from the hands of the person in whom society has invested about \$125,000 to teach him to do what he does; from the hands of the person licensed and charged by the law with the responsibility.

"The loser is the public. Unfortunately I don't see any immediate solution as we go down this competitive road until the public rises up and decides it is not getting the quality it wanted. I see less enthusiasm in Washington for the regulatory model. Although HCFA, Medicare and Medicaid, are regulatory minded, only one of the candidates for President, for example, could be described as regulatory zealot. So far as we know. But the competitive road is our biggest worry right now. By competitive I mean, of course, the pressure to cut costs without much regard to consequences.

"Again, our best hope is to provide excellence at every turn and thus convince the public that private interests can do it better than government or other interlopers. Still another aspect of the story we need to tell is the amount of time physicians are forced to spend carrying out tasks that don't involve patient-care decisions. That is inefficient from society's standpoint. It's wasteful. I spend two hours a day handling tele-

phone calls on matters that don't involve patient care. And the time is going up, as I see it.

"It's all part of shifting the burden of administrative services away from those who pay the bills to those who provide the services. And it is by design."

Q: A final word then on the success or failure of alternatives to traditional care. Taking the long view, what do you foresee?

A: "Again, Americans do have more choices than ever before. Prepaid plans are not bad *per se*. They have a place in the scheme of things. For some people — the young, for example — in some circumstances, they may be appropriate. But they have a built-in limitation, an intrinsic flaw, that restricts their success. Basically, they are all plans for rationing, at one level or another, and by one device or another. Those that deliver quality care, and some may, are not to be scorned. Those that don't deliver quality and place patients at risk — those are not only to be discouraged but they are to be actively opposed.

"In whatever configuration care is delivered, the one test that should concern organized medicine is quality of the product. That means we should not, for example, discourage all HMO efforts, because some of them may do very well. What we want to drive from the market are those that do not have the patient's interest at heart, those that exploit patients.

"I am comfortable with the HMO concept as long as it provides quality care; I am uncomfortable with it when the reverse is true, when services are withheld for economic reasons.

"But exploitation can also occur on the fee-for-service side when services are expanded inappropriately."

All of which provides a fair sampling of Dr. Leitner's reflections on a wide range of topics. In his comments you may see traces of his early life on that South Carolina farm and perhaps just a tad here and there of the engineer insisting on qualitative and quantitative analysis at every juncture.

If so, all the more reason Alabama physicians should benefit by Dr. Leitner's year as MASA President.



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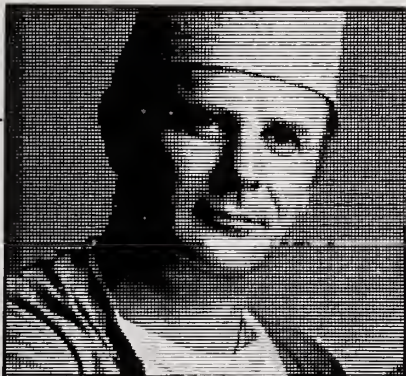
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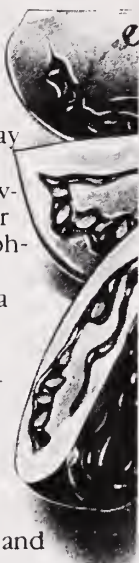
Be moderate in consumption of alcohol also.

A good rule of thumb is cut down on fat and don't be fat. Weight reduction may lower cancer risk. Our 12-year study of nearly a million Americans uncovered high cancer risks particularly among people 40% or more overweight.

Now, more than ever, we know you can cook up your own defense against cancer. So eat healthy and be healthy.

No one faces
cancer alone.

 AMERICAN CANCER SOCIETY®



YOCON® YOHIMBINE HCl

Description: Yohimbine is a 3a-15a-20B-17a-hydroxy Yohimbine-16a-carboxylic acid methyl ester. The alkaloid is found in Rubaceae and related trees. Also in Rauwolfia Serpentina (L) Benth. Yohimbine is an indolalkylamine alkaloid with chemical similarity to reserpine. It is a crystalline powder, odorless. Each compressed tablet contains (1/12 gr.) 5.4 mg of Yohimbine Hydrochloride.

Action: Yohimbine blocks presynaptic alpha-2 adrenergic receptors. Its action on peripheral blood vessels resembles that of reserpine, though it is weaker and of short duration. Yohimbine's peripheral autonomic nervous system effect is to increase parasympathetic (cholinergic) and decrease sympathetic (adrenergic) activity. It is to be noted that in male sexual performance, erection is linked to cholinergic activity and to alpha-2 adrenergic blockade which may theoretically result in increased penile inflow, decreased penile outflow or both.

Yohimbine exerts a stimulating action on the mood and may increase anxiety. Such actions have not been adequately studied or related to dosage although they appear to require high doses of the drug. Yohimbine has a mild anti-diuretic action, probably via stimulation of hypothalamic centers and release of posterior pituitary hormone.

Reportedly, Yohimbine exerts no significant influence on cardiac stimulation and other effects mediated by B-adrenergic receptors, its effect on blood pressure, if any, would be to lower it; however no adequate studies are at hand to quantitate this effect in terms of Yohimbine dosage.

Indications: Yocon® is indicated as a sympatholytic and mydriatic. It may have activity as an aphrodisiac.

Contraindications: Renal diseases, and patient's sensitive to the drug. In view of the limited and inadequate information at hand, no precise tabulation can be offered of additional contraindications.

Warning: Generally, this drug is not proposed for use in females and certainly must not be used during pregnancy. Neither is this drug proposed for use in pediatric, geriatric or cardio-renal patients with gastric or duodenal ulcer history. Nor should it be used in conjunction with mood-modifying drugs such as antidepressants, or in psychiatric patients in general.

Adverse Reactions: Yohimbine readily penetrates the (CNS) and produces a complex pattern of responses in lower doses than required to produce peripheral a-adrenergic blockade. These include, anti-diuresis, a general picture of central excitation including elevation of blood pressure and heart rate, increased motor activity, irritability and tremor. Sweating, nausea and vomiting are common after parenteral administration of the drug.^{1,2} Also dizziness, headache, skin flushing reported when used orally.^{1,3}

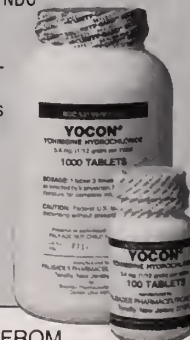
Dosage and Administration: Experimental dosage reported in treatment of erectile impotence.^{1,3,4} 1 tablet (5.4 mg) 3 times a day, to adult males taken orally. Occasional side effects reported with this dosage are nausea, dizziness or nervousness. In the event of side effects dosage to be reduced to 1/2 tablet 3 times a day, followed by gradual increases to 1 tablet 3 times a day. Reported therapy not more than 10 weeks.³

How Supplied: Oral tablets of Yocon® 1/12 gr. 5.4 mg in bottles of 100's NDC 53159-001-01 and 1000's NDC 53159-001-10.

References:

1. A. Morales et al., New England Journal of Medicine: 1221, November 12, 1981.
2. Goodman, Gilman — The Pharmacological basis of Therapeutics 6th ed., p. 176-188. McMillan December Rev. 1/85.
3. Weekly Urological Clinical letter, 27:2, July 4, 1983.
4. A. Morales et al., The Journal of Urology 128: 45-47, 1982.

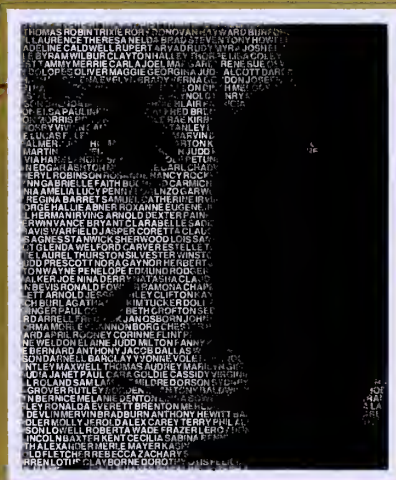
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In a recent survey, 4,120 participating physicians gave us their views¹ on **INDERAL LA** in the treatment of hypertension, angina and migraine.

INDERAL LA is their preferred beta blocker

...of the nearly three out of four physicians responding to the questionnaire, an impressive 97% rated **INDERAL LA** good to excellent for overall performance. Virtually all cited efficacy, tolerability, long-term cardiovascular protection and once-daily convenience as important factors in their choosing to prescribe **INDERAL LA**.

INDERAL LA promotes patient compliance

...Virtually every responding physician rated patient satisfaction with **INDERAL LA** to be as good as, or better than, other beta blockers.

Like conventional **INDERAL** Tablets, **INDERAL LA** should not be used in the presence of congestive heart failure, sinus bradycardia, cardiogenic shock, heart block greater than first degree and bronchial asthma.

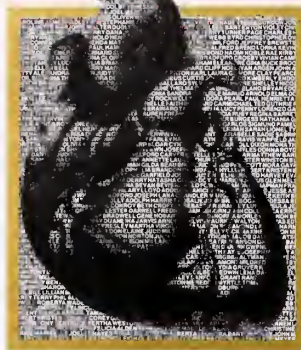
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Please see next page for brief summary of prescribing information.

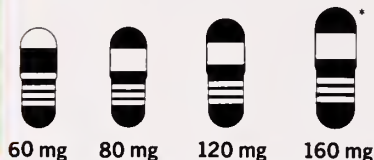
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LONG-ACTING CAPSULES
60, 80, 120, 160 mg

The one you know best
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BRIEF SUMMARY (FOR FULL PRESCRIBING INFORMATION, SEE PACKAGE CIRCULAR.)

INDERAL[®] LA brand of propranolol hydrochloride (Long Acting Capsules)

DESCRIPTION. INDERAL LA is formulated to provide a sustained release of propranolol hydrochloride. INDERAL LA is available as 60 mg, 80 mg, 120 mg, and 160 mg capsules.

CLINICAL PHARMACOLOGY. INDERAL is a nonselective, beta-adrenergic receptor-blocking agent possessing no other autonomic nervous system activity. It specifically competes with beta-adrenergic receptor-stimulating agents for available receptor sites. When access to beta-receptor sites is blocked by INDERAL, the chronotropic, inotropic, and vasodilator responses to beta-adrenergic stimulation are decreased proportionately.

INDERAL LA Capsules (60, 80, 120, and 160 mg) release propranolol HCl at a controlled and predictable rate. Peak blood levels following dosing with INDERAL LA occur at about 6 hours and the apparent plasma half-life is about 10 hours. When measured at steady state over a 24-hour period the areas under the propranolol plasma concentration-time curve (AUCs) for the capsules are approximately 60% to 65% of the AUCs for a comparable divided daily dose of INDERAL Tablets. The lower AUCs for the capsules are due to greater hepatic metabolism of propranolol, resulting from the slower rate of absorption of propranolol. Over a twenty-four (24) hour period, blood levels are fairly constant for about twelve (12) hours then decline exponentially.

INDERAL LA should not be considered a simple mg-for-mg substitute for conventional propranolol and the blood levels achieved do not match (are lower than) those of two to four times daily dosing with the same dose. When changing to INDERAL LA from conventional propranolol, a possible need for retitration upwards should be considered especially to maintain effectiveness at the end of the dosing interval. In most clinical settings, however, such as hypertension or angina where there is little correlation between plasma levels and clinical effect, INDERAL LA has been therapeutically equivalent to the same mg dose of conventional INDERAL as assessed by 24-hour effects on blood pressure and on 24-hour exercise responses of heart rate, systolic pressure, and rate pressure product. INDERAL LA can provide effective beta blockade for a 24-hour period.

INDICATIONS AND USAGE. Hypertension: INDERAL LA is indicated in the management of hypertension; it may be used alone or used in combination with other antihypertensive agents, particularly a thiazide diuretic. INDERAL LA is indicated in the management of hypertensive emergencies.

Angina Pectoris Due to Coronary Atherosclerosis: INDERAL LA is indicated for the long-term management of patients with angina pectoris.

Migraine: INDERAL LA is indicated for the prophylaxis of common migraine headache. The efficacy of propranolol in the treatment of a migraine attack that has started has not been established and propranolol is not indicated for such use.

Hypertrophic Subaortic Stenosis: INDERAL LA is useful in the management of hypertrophic subaortic stenosis, especially for treatment of exertional or other stress-induced angina, palpitations, and syncope. INDERAL LA also improves exercise performance. The effectiveness of propranolol hydrochloride in this disease appears to be due to a reduction of the elevated outflow pressure gradient which is exacerbated by beta-receptor stimulation. Clinical improvement may be temporary.

CONTRAINDICATIONS. INDERAL is contraindicated in 1) cardiogenic shock; 2) sinus bradycardia and greater than first-degree block; 3) bronchial asthma; 4) congestive heart failure (see WARNINGS) unless the failure is secondary to a tachyarrhythmia treatable with INDERAL.

WARNINGS. CARDIAC FAILURE: Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive heart failure, and its inhibition by beta blockade may precipitate more severe failure. Although beta blockers should be avoided in overt congestive heart failure, if necessary, they can be used with close follow-up in patients with a history of failure who are well compensated and are receiving digitalis and diuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitalis on heart muscle.

IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta blockers can, in some cases, lead to cardiac failure. Therefore, at the first sign or symptom of heart failure, the patient should be digitalized and/or treated with diuretics, and the response observed closely, or INDERAL should be discontinued (gradually, if possible).

IN PATIENTS WITH ANGINA PECTORIS, there have been reports of exacerbation of angina and, in some cases, myocardial infarction, following abrupt discontinuance of INDERAL therapy. Therefore, when discontinuance of INDERAL is planned, the dosage should be gradually reduced over at least a few weeks, and the patient should be cautioned against interruption or cessation of therapy without the physician's advice. If INDERAL therapy is interrupted and exacerbation of angina occurs, it usually is advisable to reinstitute INDERAL therapy and take other measures appropriate for the management of unstable angina pectoris. Since coronary artery disease may be unrecognized, it may be prudent to follow the above advice in patients considered at risk of having occult atherosclerotic heart disease who are given propranolol for other indications.

Nonallergic Bronchospasm (eg, chronic bronchitis, emphysema)—PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD IN GENERAL NOT RECEIVE BETA BLOCKERS. INDERAL should be administered with caution since it may block bronchodilation produced by endogenous and exogenous catecholamine stimulation of beta receptors.

MAJOR SURGERY: The necessity or desirability of withdrawal of beta-blocking therapy prior to major surgery is controversial. It should be noted, however, that the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.

INDERAL (propranolol HCl), like other beta blockers, is a competitive inhibitor of beta-receptor agonists and its effects can be reversed by administration of such agents, eg, dobutamine or isoproterenol. However, such patients may be subject to protracted severe hypotension. Difficulty in starting and maintaining the heartbeat has also been reported with beta blockers.

DIABETES AND HYPOGLYCEMIA: Beta blockers should be used with caution in diabetic patients if a beta-blocking agent is required. Beta blockers may mask tachycardia occurring with hypoglycemia, but other manifestations such as dizziness and sweating may not be significantly affected. Following insulin-induced hypoglycemia, propranolol may cause a delay in the recovery of blood glucose to normal levels.

THYROTOXICOSIS: Beta blockade may mask certain clinical signs of hyperthyroidism. Therefore, abrupt withdrawal of propranolol may be followed by an exacerbation of symptoms of hyperthyroidism, including thyroid storm. Propranolol may change thyroid function tests, increasing T_4 and reverse T_3 , and decreasing T_3 .

IN PATIENTS WITH WOLFF-PARKINSON-WHITE SYNDROME, several cases have been reported in which, after propranolol, the tachycardia was replaced by a severe bradycardia requiring a demand pacemaker. In one case this resulted after an initial dose of 5 mg propranolol.

PRECAUTIONS. GENERAL: Propranolol should be used with caution in patients with impaired hepatic or renal function. INDERAL (propranolol HCl) is not indicated for the treatment of hypertensive emergencies.

Beta-adrenoreceptor blockade can cause reduction of intraocular pressure. Patients should be told that INDERAL may interfere with the glaucoma screening test. Withdrawal may lead to a return of increased intraocular pressure.

CLINICAL LABORATORY TESTS: Elevated blood urea levels in patients with severe heart disease, elevated serum transaminase, alkaline phosphatase, lactate dehydrogenase.

DRUG INTERACTIONS: Patients receiving catecholamine-depleting drugs such as reserpine should be closely observed if INDERAL (propranolol HCl) is administered. The added catecholamine-blocking action may produce an excessive reduction of resting sympathetic nervous activity which may result in hypotension, marked bradycardia, vertigo, syncopal attacks, or orthostatic hypotension.

Caution should be exercised when patients receiving a beta blocker are administered a calcium-channel-blocking drug, especially intravenous verapamil, for both agents may depress myocardial contractility or atrioventricular conduction. On rare occasions, the concomitant intravenous use of a beta blocker and verapamil has resulted in serious adverse reactions, especially in patients with severe cardiomyopathy, congestive heart failure, or recent myocardial infarction.

Aluminum hydroxide gel greatly reduces intestinal absorption of propranolol.

Ethanol slows the rate of absorption of propranolol.

Phenyltoin, phenobarbital, and rifampin accelerate propranolol clearance.

Chlorpromazine, when used concomitantly with propranolol, results in increased plasma levels of both drugs.

Antipyrine and lidocaine have reduced clearance when used concomitantly with propranolol.

Thyroxine may result in a lower than expected T_3 concentration when used concomitantly with propranolol.

Cimetidine decreases the hepatic metabolism of propranolol, delaying elimination and increasing blood levels.

Theophylline clearance is reduced when used concomitantly with propranolol.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY: Long-term studies in animals have been conducted to evaluate toxic effects and carcinogenic potential. In 18-month studies in both rats and mice, employing doses up to 150 mg/kg/day, there was no evidence of significant drug-induced toxicity. There were no drug-related tumorigenic effects at any of the dosage levels. Reproductive studies in animals did not show any impairment of fertility that was attributable to the drug.

PREGNANCY: Pregnancy Category C. INDERAL has been shown to be embryotoxic in animal studies at doses about 10 times greater than the maximum recommended human dose.

There are no adequate and well-controlled studies in pregnant women. INDERAL should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

NURSING MOTHERS: INDERAL is excreted in human milk. Caution should be exercised when INDERAL is administered to a nursing woman.

PEDIATRIC USE: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS. Most adverse effects have been mild and transient and have rarely required the withdrawal of therapy.

Cardiovascular: Bradycardia; congestive heart failure; intensification of AV block; hypotension; paresthesia of hands; thrombocytopenic purpura; arterial insufficiency, usually of the Raynaud type.

Central Nervous System: Light-headedness; mental depression manifested by insomnia, lassitude, weakness, fatigue; reversible mental depression progressing to cataplexy; visual disturbances; hallucinations; vivid dreams; an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics. For immediate formulations, fatigue, lethargy, and vivid dreams appear dose related.

Gastrointestinal: Nausea, vomiting, epigastric distress, abdominal cramping, diarrhea, constipation, mesenteric arterial thrombosis, ischemic colitis.

Allergic: Pharyngitis and agranulocytosis, erythematous rash, fever combined with aching and sore throat, laryngospasm and respiratory distress.

Respiratory: Bronchospasm.

Hematologic: Agranulocytosis, nonthrombocytopenic purpura, thrombocytopenic purpura.

Auto-immune: In extremely rare instances, systemic lupus erythematosus has been reported.

Miscellaneous: Alopecia, LE-like reactions, psoriasisiform rashes, dry eyes, male impotence, and Peyronie's disease have been reported rarely. Oculomucocutaneous reactions involving the skin, serous membranes and conjunctivae reported for a beta blocker (practolol) have not been associated with propranolol.

DOSAGE AND ADMINISTRATION. INDERAL LA provides propranolol hydrochloride in a sustained-release capsule for administration once daily. If patients are switched from INDERAL Tablets to INDERAL LA Capsules, care should be taken to assure that the desired therapeutic effect is maintained. INDERAL LA should not be considered a simple mg-for-mg substitute for INDERAL. INDERAL LA has different kinetics and produces lower blood levels. Retitration may be necessary, especially to maintain effectiveness at the end of the 24-hour dosing interval.

HYPERTENSION—Dosage must be individualized. The usual initial dosage is 80 mg INDERAL LA once daily, whether used alone or added to a diuretic. The dosage may be increased to 120 mg once daily or higher until adequate blood pressure control is achieved. The usual maintenance dosage is 120 to 160 mg once daily. In some instances a dosage of 640 mg may be required. The time needed for full hypertensive response to a given dosage is variable and may range from a few days to several weeks.

ANGINA PECTORIS—Dosage must be individualized. Starting with 80 mg INDERAL LA once daily, dosage should be gradually increased at three- to seven-day intervals until optimal response is obtained. Although individual patients may respond at any dosage level, the average optimal dosage appears to be 160 mg once daily. In angina pectoris, the value and safety of dosage exceeding 320 mg per day have not been established.

If treatment is to be discontinued, reduce dosage gradually over a period of a few weeks (see WARNINGS).

MIGRAINE—Dosage must be individualized. The initial oral dose is 80 mg INDERAL LA once daily. The usual effective dose range is 160-240 mg once daily. The dosage may be increased gradually to achieve optimal migraine prophylaxis. If a satisfactory response is not obtained within four to six weeks after reaching the maximal dose, INDERAL LA therapy should be discontinued. It may be advisable to withdraw the drug gradually over a period of several weeks.

HYPERTROPHIC SUBAORTIC STENOSIS—80-160 mg INDERAL LA once daily.

PEDIATRIC DOSAGE—At this time the data on the use of the drug in this age group are too limited to permit adequate directions for use.

*The appearance of these capsules is a registered trademark of Ayerst Laboratories.

Reference:

1. Data on file, Ayerst Laboratories.

D7295/188

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1987 Medical Foundation Builders

The Medical Foundation of Alabama gratefully acknowledges the contributions it received during 1987 and further encourages all physicians to consider a gift to the Foundation this year.

The non-profit corporation was created to address new problems facing medicine and to sponsor solutions that could not otherwise be adequately funded by the Medical Association.

During the past year, the Foundation has helped purchase television production equipment to be used to compile video tape programs for Continuing Medical Education, AIDS information materials, and public service announcements; has supported the Impaired Physicians Program; and has purchased, and distributed to each MASA member, an outstanding publi-

cation detailing much of the knowledge currently available about AIDS.

Listed below are the physicians who made contributions to the Foundation during the period from January 1 to December 31, 1987.

Gifts to the Medical Foundation of Alabama are received in a variety of ways: bequests, memorials, real estate, stock and monetary contributions. Contributing memberships to the Foundation are \$100 per year. All gifts are tax deductible.

Direct all correspondence to the Foundation to MASA Public Relations Director, Mr. Holley Midgley, Medical Foundation of Alabama, P.O. Box 1900-C, Montgomery, AL 36197.

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Gas Gangrene

Recent Experience in Huntsville

LeRoy F. Harris, M.D.*

Abstract

Gas gangrene is a gangrenous infection of muscle caused most frequently by *Clostridium perfringens* and less often by *C. novyi* and *C. septicum*. Other nonclostridial organisms may be isolated as well. It usually is a sequel to trauma, surgical intervention or vascular insufficiency in diabetics and may arise spontaneously or follow abortion. Clinical manifestations include pain, dusky and bronzed overlying skin with bullae, crepitance, tachycardia out of proportion to the slight temperature elevation, hypotension and mental clarity with a fear of impending demise. The underlying muscle becomes frankly necrotic with loss of contractility. The diagnosis is suspected clinically and confirmed by gram-stain and culture of the involved muscle. Management consists of surgical debridement, appropriate antimicrobial therapy and supportive measures. The use of hyperbaric oxygen is unsettled and gas gangrene antitoxin no longer is available commercially. The mortality rate has ranged from 0 to 60 percent.

Gas gangrene, or clostridial myonecrosis, a rapidly progressive, life-threatening infection of skeletal muscle caused by clostridial organisms. Its incidence varies considerably with different environments. The infection was estimated to have killed over 100,000 troops during World War I but only 22 cases were reported during eight years of the Viet Nam conflict.¹ A recent review estimated a yearly occurrence of over 3000 cases in the United States,² yet few physicians encounter and even fewer recognize a case of gas gangrene. We review our experience with gas gangrene in a single city-county hospital to remind physicians of this most malignant of infections.

Materials and Methods

We reviewed the charts of all patients discharged from Huntsville Hospital, Huntsville, Alabama, with a diagnosis of gas gangrene for the seven year period of 1981 through 1987, inclusive. Gas gangrene was defined as a gangrenous infection of muscle caused by clostridia. Clostridia were identified as spore-forming, gram-positive bacilli which grew anaerobically and formed colonies which were surrounded by a zone of hemolysis on blood agar plate and which emitted a putrid odor. Final identification was made by the Ana-Dent® (API, Plainview, New York).

*Clinical Associate Professor of Medicine, School of Primary Medical Care, University of Alabama in Huntsville, Suite A, 101 Bob Wallace, Huntsville, Alabama 35801.

Results

Table 1 described the clinical features of four cases of gas gangrene. The patients ranged in age from 19 to 80 years and averaged 48 years. There were two females and two males. Underlying diseases and precipitating causes of gas gangrene included arterial insufficiency, diabetes mellitus, elective abortion, colon cancer and gunshot wound. The maximum temperature on the first day gas gangrene was diagnosed extended from 99.6° to 103° F and averaged 101.6° F. The infection involved the leg, uterus, arm, perineum and abdominal wall.

Table 2 lists the laboratory data, treatment, complications and outcome of four cases of gas gangrene. The clostridial species isolated consisted of *C. perfringens* in two cases and *C. septicum* and *C. innocuum* in one case each, respectively. The leukocyte count on the first day gas gangrene was diagnosed ranged from 5270 to 33600 per cu mm and averaged 18500 per cu mm. Treatment in all patients comprised administration of penicillin or ampicillin, as well as other antimicrobial agents, and three patients underwent surgical procedures including above the knee amputation, total abdominal hysterectomy and bilateral salpingo-oophorectomy and excision of the abdominal wall. Complications developed in all patients and consisted of acute renal failure in all patients and hemolytic anemia and respiratory failure in one patient each, respectively. Three of the patients died for a 75 percent mortality rate.

Discussion

Clostridia are gram-positive, spore-forming, anaerobic rods present in soil, animals and the gastrointestinal and female genital tract of humans. Over 60 species of clostridia are recognized and approximately 30 species are responsible for human infections. Although growth proceeds better under anaerobic conditions, some clostridial species, especially *C. perfringens*, are remarkably aerotolerant. Clostridia produce a variety of toxins which mediate infections caused by these organisms.³

Gas gangrene is a gangrenous infection of muscle caused by clostridia. Individual lesions often yield more than one species of clostridia as well as other non-clostridial bacteria. Clostridia isolated from patients with gas gangrene include most commonly *C. perfringens* (80 percent) followed by *C. novyi* (40) percent and *C. septicum* (20 percent).⁴ In our series *C. perfringens* was cultured from two patients and *C. septicum* and *C. innocuum* were isolated from one patient each, respectively.

The pathogenesis of gas gangrene involves a lowering of the oxidation-reduction potential due to trauma, ischemia, pyogenic infection or the presence of a foreign

body. Clostridial spores introduced into such an environment convert to vegetative forms and release exotoxins which cause rapidly progressive muscle necrosis. An intense edema develops around the gangrenous muscle which further compromises blood supply.^{2,4}

Historically gas gangrene has been associated with warfare and resulting traumatic wounds, gross contamination and delay in surgical debridement. During peacetime gas gangrene is a sequel to one of three conditions: trauma, surgical intervention or vascular insufficiency. Gas gangrene after trauma often follows an automobile accident and involves the extremities of young males who acquire the organism exogenously. The prognosis is relatively favorable. Patients who acquire gas gangrene postoperatively also are predominately male but older than trauma victims. The surgical procedures usually involve the bowel or biliary tract and the infection often is located in the abdominal wall and viscera. The infection is thought to be introduced endogenously and the outlook is poorer. Gas gangrene as a consequence of arterial insufficiency usually afflicts elderly diabetics and occurs in the lower extremities.⁵

Less common variants of gas gangrene include a nontraumatic variety and uterine gas gangrene. Nontraumatic gas gangrene arises spontaneously without an obvious source. *C. perfringens* is the predominant pathogen and when *C. septicum* is isolated there is a remarkable association with a silent carcinoma, usually of the colon. The majority of patients with nontraumatic gas gangrene suffer a rapid demise. Uterine gas gangrene usually results from criminal abortion but has been documented to follow normal delivery.³ Gas gangrene in our patients developed in the abdominal wall following a gunshot wound, in the leg as a consequence of arterial insufficiency and diabetes mellitus, spontaneously in the arm, leg and perineum in a patient with colon cancer and in the uterus subsequent to an elective abortion.

The initial clinical manifestation of gas gangrene is increasing pain in the infected area which spread as the infection enlarges. Local edema, swelling and tenderness with a thin hemorrhagic fluid appears and the overlying skin becomes tense and white followed by dusky and bronzed. Bullae containing a dark red or purple discharge are noted and crepitation is appreciated. A peculiar sweet odor suggestive of gas gangrene has been described. Systemic signs comprise tachycardia out of proportion to the slight temperature elevation, hypotension, ashen gray pallor and diaphoresis. Mental clarity with fear of impending demise is succeeded by a toxic delirium.¹

The underlying muscle is at first pale and edematous and then as the blood supply is lost it becomes brick

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Gas Gangrene

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red, mottled purple and frankly necrotic. Muscle contractility is lost and gas is detected. Jaundice is discovered when gas gangrene involves the uterus but rarely when it is located in wounds.¹

The diagnosis of gas gangrene is suspected on clinical grounds and confirmed by direct visualization of the affected muscle. Gram-stained smear of the exudate reveals large gram-positive rods. In tissue *C. perfringens* does not demonstrate spores while the other toxigenic clostridia often sporulate. Isolation of clostridia in anaerobic culture combined with a typical clinical picture establishes the diagnosis of gas gangrene.⁴ Approximately 15 percent of blood cultures are positive.³ Additional laboratory data consist of anemia, leukocytosis, renal insufficiency and hepatic dysfunction.⁵ In our series hemolytic anemia developed in one patient, leukocytosis was impressive in three patients and acute renal failure occurred in all patients including one patient who experienced concomitant respiratory failure.

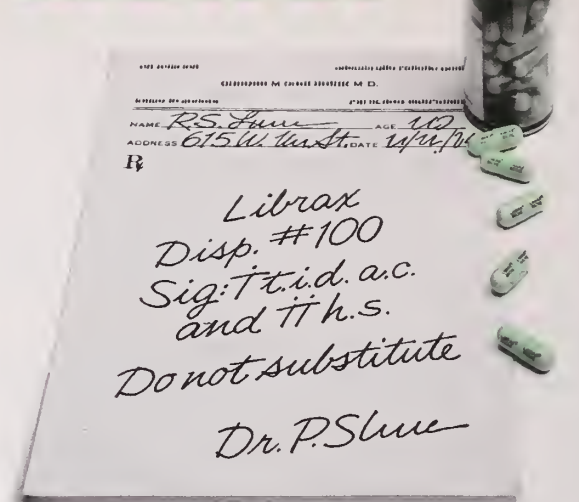
The differential diagnosis features clostridial infections other than gas gangrene and nonclostridial gangrenous and crepitant cellulitis. Clostridial cellulitis in the absence of associated myositis has a more gradual onset and displays less systemic effects than gas gangrene.⁶ As its name implies, nonclostridial gangrenous and crepitant cellulitis is characterized by extensive necrosis of tissue and production of discernible quantities of tissue gas. Some of the more common clinical entities which compose this group of infections include nonclostridial crepitant cellulitis, necrotizing fasciitis, progressive bacterial synergistic gangrene, nonclostridial myositis and synergistic necrotizing cellulitis.⁷

The management of gas gangrene involves three crucial elements: surgical debridement, appropriate antimicrobial therapy and supportive measure. Emergency surgical exploration is indicated both to determine the nature and extend of the process and to accomplish extensive surgical excision of infected muscles. When gas gangrene is located in an extremity amputation often is required. Antibiotic administration serves as an important adjunct to surgery with high dose intravenous penicillin G the agent of choice. In the penicillin-allergic patient chloramphenicol is substituted. Clostridia in vitro are susceptible to metronidazole but clinical experience with this drug is lacking. Additional antimicrobial agents are added to provide coverage for coexisting nonclostridial pathogens. Ancillary care consists of attention to fluid and electrolyte balance, adequate oxygenation and maintenance of sufficient blood volume.^{4, 8} Three of our patients were subjected to surgical procedures and all received parenteral penicillin or ampicillin therapy.

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Gas Gangrene

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The use of hyperbaric oxygen in gas gangrene is unsettled. Under laboratory conditions hyperbaric oxygen is capable of destroying clostridia and inhibiting their toxin production. Unfortunately no double-blind, controlled trials utilizing hyperbaric oxygen therapy have been performed. Using combined surgical, antimicrobial and hyperbaric oxygen treatment, various authors have reported mortality rates ranging from 0 to 53 percent and averaging 25 percent² which compares favorably to the results of series without hyperbaric oxygen.^{5, 6} The complications of hyperbaric oxygen therapy, although infrequent, comprise oxygen toxicity, barotrauma, decompression sickness, lung damage and fire.² The most appropriate indication for hyperbaric oxygen appears to be when gas gangrene involves the abdominal wall in order to forestall mutilating surgery.^{3, 8} The efficacy of polyvalent gas gangrene antitoxin is controversial and it no longer is available commercially.⁸

The mortality rate of gas gangrene has ranged from 0 to 60 percent^{2, 3, 6} and in our series was 75 percent. The prognosis adversely is affected when gas gangrene is located in the abdominal wall and when it occurs

in the elderly. Laboratory parameters which connote a poor outlook include a normal or depressed white blood cell count, decreased platelet count and abnormal renal or hepatic function.⁵ ■

Acknowledgement

The author thanks Juanita Spicer for preparation of the manuscript.

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TABLE 1
Gas Gangrene — Clinical Features

Patient No.	Age/Sex (years)	Underlying disease, precipitating cause	T max (°F)	Area involved
1	67/F	Arterial insufficiency, diabetes mellitus	102.8	Leg
2	19/F	Elective Abortion	101	Uterus
3	80/M	Colon cancer	99.6	Arm, leg, perineum
4	26/M	Gunshot wound	103	Abdominal wall

Note: T max = maximum temperature on first day gas gangrene diagnosed.

TABLE 2
Gas Gangrene — Laboratory Data, Treatment, Complications, Outcome

Patient No.	Clostridal species	WBC (cells/cu mm)	Treatment	Complications	Outcome
1	<i>perfringens</i>	27000	AKA, penicillin	ARF	Die
2	<i>perfringens</i>	33600	TAH, BSO ampicillin	ARF, hemolytic anemia	Survive
3	<i>septicum</i>	32440	Penicillin	ARF	Die
4	<i>innocuum</i>	5270	Excision pencillin	ARF, respiratory failure	Die

Note: WBC = leukocyte count on first day gas gangrene diagnosed. AKA = above the knee amputation, ARF = acute renal failure, TAH = total abdominal hysterectomy, BSO = bilateral salpingo-oophorectomy.

Sphenoid Sinusitis: The Importance of CT Scanning

Robert L. Baldwin, M.D.*

Lev Bragg, M.D.†

Abstract

Sphenoid sinusitis is an uncommon and perhaps overlooked infection. Symptoms may be non-specific for sinus disease. Diagnosis of sphenoid sinusitis can be difficult when using conventional radiographic techniques, due to superimposition of surrounding bony structures. Three cases of sphenoid sinusitis are presented in which conventional sinus x-rays appeared normal; diagnosis was confirmed with CT scanning. A CT scan of the sinuses should be obtained in cases where this diagnosis is suspect, even when conventional radiographic studies reveal no disease.

Introduction

Current diagnosis of sphenoid sinusitis is uncommon, representing less than 3% of all sinus infections. The true incidence, however, of sphenoid sinusitis infection is certainly higher, as many cases are not identified with conventional sinus films. Sphenoid sinusitis may be associated with radiographic evidence of infection in other paranasal sinuses. When treatment is initiated for other sinus infection, the sphenoid may clear without recognition. The following three cases illustrate the occult nature of this disease and the inability to rely on conventional films for diagnosis.

Case Presentations

Case #1: A 35-year-old female presented with a two week history of severe retro-orbital and temporal headaches exacerbated by changing head positions, especially leaning forward. Physical examination was normal. Conventional sinus x-rays, seen in Figures 1A and 1B, were read as normal. A CT scan, seen in

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*Clinical Professor, Otolaryngology, University of Alabama at Birmingham School of Medicine, Birmingham, Alabama.

†University of Alabama at Birmingham School of Medicine, Birmingham, Alabama. Correspondent author: Lev Bragg, M.D., St. Vincent's Professional Building II, 2700 10th Avenue South, Suite 502, Birmingham, Alabama 35205. Telephone: (205) 933-2951.

Sphenoid Sinusitis

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Figure 1A: Conventional lateral view of Case #1, read as normal.

Clinically, the typical headache may be described as involving pain from the vertex, fronto-temporal, retro-orbital, and parietal or occipital areas. The headache is usually severe, progressive in intensity, interferes with sleep, and is not relieved by aspirin. The pain is often exacerbated by changing head position, especially leaning forward.

Table 1 lists the most frequent presentations of thirty-one patients with infections of the sphenoid sinus. Physical examination may confirm the source of these symptoms, with demonstration of nasal congestion, purulent drainage from the superior meatus or pus in



Figure 1B: Conventional Waters view of Case #1, read as normal.

TABLE 1
Sphenoid Sinusitis Presentation — 31 Patients

Headache	31
Purulent Rhinorrhea	19
Orbital Abscess	8
Meningitis	4
Orbital Apex Syndrome	1
Cavernous Sinus Thrombosis	1

the sphenoid sinus ostium. Paresthesia of the V1, V2, or V3 dermatomes may also be seen. Headache was present in all thirty-one patients; purulent rhinorrhea was seen in nineteen.

Such varied presenting symptoms are due to the many vital structures adjacent to the sphenoid sinus; these structures may be affected by the infectious process. Several structures are so intimately related to the sphenoid sinus that their function is jeopardized by infection. These include the dura, the pituitary gland, the cavernous sinus, the carotid artery, the sphenopalatine ganglion, nerve and artery, Cranial Nerves II, III, IV, VI, V1 and V2. Depending on the thickness of the walls of the sinus, these structures may become involved early or late in the disease process. Prompt recognition and treatment is imperative to avoid complications. If treatment is delayed, symptomatology may progress to orbital abscess, meningitis, orbital apex syndrome or cavernous sinus thrombosis.

Complications of sphenoid sinusitis are listed in Table 2, which includes fifteen patients with acute sphenoid sinusitis.

TABLE 2
Sphenoid Sinusitis Complications

	<i>Acute</i>	<i>Chronic</i>
Orbital Cellulitis	1	1
Unilateral Ophthalmoplegia	1	1
Meningitis	6	0
Cavernous Sinus Thrombosis	5	1

noid sinusitis and fifteen with chronic sphenoid infections. Major complications included meningitis and cavernous sinus thrombosis; orbital abscess, unilateral ophthalmoplegia and cortical vein thrombosis also occurred. Five patients developed irreversible cranial nerve injury and four died.

Because of the location and intimate relationship of the sphenoid sinus with many important deep facial and intracranial structures, disease in this area is a diagnostic challenge, both clinically and radiographically. Routine sinus x-rays are often not adequate, due to superimposition of surrounding bony structures. The Caldwell view allows visualization of the lesser wing of the sphenoid, the orbital surface of the greater wing of the sphenoid, and the superior orbital fissure. The sphenoid sinus, however, is hidden by the nasal turbinates and the ethmoid sinuses. The lateral view allows visualization of the superior portion of the sinus as well as the indentations produced by the carotid artery. The Caudal surface of the sinus may be hidden by the greater wing of the sphenoid on the lateral view.

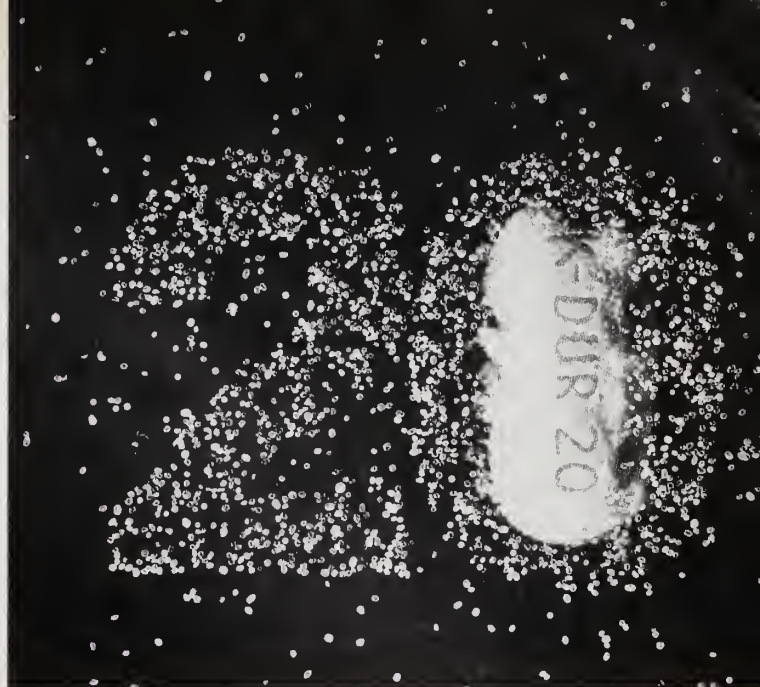
The submental vertex view demonstrates the size of each sphenoid sinus, the lateral walls and septum, and the junction of the sphenoid and ethmoid sinuses. The lateral and submental vertex views best identify pathology with the sphenoid sinus. The sphenoid sinus may be seen on the Water's view if taken with the mouth open.

Polytomography has been used to evaluate the sphenoid sinus, when the findings on plain films are suggestive of pathology or when more detail was deemed necessary to identify bone destruction. Most clinicians now feel that CT scanning is equal to polytomography for evaluating bone destruction and is superior for evaluation of soft tissue lesions.

Figure 2, revealed opacification of the right sphenoid sinus. She was hospitalized and treated with IV antibiotics, resulting in prompt resolution of her headache. Repeat CT scan revealed clearing of the sphenoid sinus.

Case #2: A 55-year-old male reported a one year history of frontal and occipital headaches of increasing intensity. Physical examination was normal as were conventional films. A CT scan revealed opacification of the right sphenoid sinus. Antibiotic therapy failed to resolve his symptoms, and a transseptal sphenoidotomy was performed. Thick, gelatinous material fill-

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K-DUR tablets contain micro-crystalloids which disperse upon disintegration of the tablet. These micro-crystalloids are formulated to provide a controlled release of potassium chloride. The dispersibility of the micro-crystalloids and the controlled release of ions from them are intended to minimize the possibility of a high local concentration near the gastrointestinal mucosa and the ability of the KCl to cause stenosis or ulceration. Other means of accomplishing this (e.g., incorporation of potassium chloride into a wax matrix) have reduced the frequency of such lesions to less than one per 100,000 patient years (compared to 40–50 per 100,000 patient years with enteric-coated potassium chloride) but have not eliminated them. The frequency of GI lesions with K-DUR tablets is, at present, unknown. K-DUR tablets should be discontinued immediately and the possibility of bowel obstruction or perforation considered if severe vomiting, abdominal pain, distention, or gastrointestinal bleeding occurs.

Metabolic Acidosis—Hypokalemia in patients with metabolic acidosis should be treated with an alkalinizing potassium salt such as potassium bicarbonate, potassium citrate, potassium acetate, or potassium gluconate.

PRECAUTIONS: The diagnosis of potassium depletion is ordinarily made by demonstrating hypokalemia in a patient with a clinical history suggesting some cause for potassium depletion. In interpreting the serum potassium level, the physician should bear in mind that acute alkalosis per se can produce hypokalemia in the absence of a deficit in total body potassium while acute acidosis per se can increase the serum potassium concentration into the normal range even in the presence of a reduced total body potassium. The treatment of potassium depletion, particularly in the presence of cardiac disease, renal disease, or acidosis requires careful attention to acid-base balance and appropriate monitoring of serum electrolytes, the electrocardiogram, and the clinical status of the patient.

Laboratory Tests: Regular serum potassium determinations are recommended. In addition, during the treatment of potassium depletion, careful attention should be paid to acid-base balance, other serum electrolyte levels, the electrocardiogram, and the clinical status of the patient, particularly in the presence of cardiac disease, renal disease, or acidosis.

Drug Interactions: Potassium-sparing diuretics; see **WARNINGS**.
Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term carcinogenicity studies in animals have not been performed.

Pregnancy Category C: Animal reproduction studies have not been conducted with K-DUR. It is also not known whether K-DUR can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. K-DUR should be given to a pregnant woman only if clearly needed.

Nursing Mothers: The normal potassium ion content of human milk is about 13 mEq per liter. Since oral potassium becomes part of the body potassium pool, so long as body potassium is not excessive, the contribution of potassium chloride supplementation should have little or no effect on the level in human milk.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: One of the most severe adverse effects is hyperkalemia (see **CONTRAINDICATIONS**, **WARNINGS**, and **OVERDOSAGE**). There have also been reports of upper and lower gastrointestinal conditions including obstruction, bleeding, ulceration, and perforation (see **CONTRAINDICATIONS** and **WARNINGS**); other factors known to be associated with such conditions were present in many of these patients.

The most common adverse reactions to oral potassium salts are nausea, vomiting, abdominal discomfort, and diarrhea. These symptoms are due to irritation of the gastrointestinal tract and are best managed by taking the dose with meals or reducing the dose.

Skin rash has been reported rarely.

OVERDOSAGE: The administration of oral potassium salts to persons with normal excretory mechanisms for potassium rarely causes serious hyperkalemia. However, if excretory mechanisms are impaired or if potassium is administered too rapidly intravenously, potentially fatal hyperkalemia can result (see **CONTRAINDICATIONS** and **WARNINGS**). It is important to recognize that hyperkalemia is usually asymptomatic and may be manifested only by an increased serum potassium concentration and characteristic electrocardiographic changes (peaking of T-waves, loss of P-waves, depression of S-T segment, and prolongation of the QT-interval). Late manifestations include muscle-paralysis and cardiovascular collapse from cardiac arrest.

Treatment measures for hyperkalemia include the following:

1. Elimination of foods and medications containing potassium and of potassium-sparing diuretics.
 2. Intravenous administration of 300 to 500 ml/hr of 10% dextrose solution containing 10–20 units of insulin per 1,000 ml.
 3. Correction of acidosis, if present, with intravenous sodium bicarbonate.
 4. Use of exchange resins, hemodialysis, or peritoneal dialysis.
- In treating hyperkalemia, it should be recalled that in patients who have been stabilized on digitalis, too rapid a lowering of the serum potassium concentration can produce digitalis toxicity.

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Sphenoid Sinusitis

continued from page 37

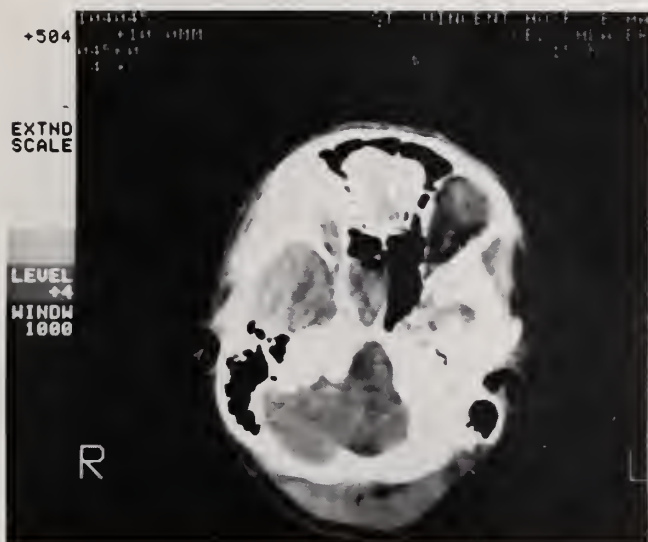


Figure 2: CT scan of Case #1, revealing opacification in the right sphenoid sinus.

ing the sinus was removed. Postoperatively, the patient noted improvement of his headaches.

Case #3: A 35-year-old male had a long history of nasal obstruction, allergic sinusitis, and severe retro-orbital headaches. Physical exam revealed a small polyp in the left nasal cavity. Sinus films appeared normal, but a CT scan revealed opacification of the left ethmoid and sphenoid sinuses as well as the nasal polyp. This patient underwent nasal polypectomy and removal of infected mucosa from the ethmoid and sphenoid sinuses. Postoperatively, he noted improvement of nasal congestion and relief of headache.

Discussion

Early in the course of infection, signs and symptoms of sphenoid sinusitis may be general and nonspecific. The most common complaint is headaches. Other less common symptoms include nasal congestion and purulent rhinorrhea. In addition, pain or paresthesia of the branches of the fifth cranial nerve and photophobia or epiphora may be early signs. In some series, up to 40% of patients have visual symptoms.

Summary

In the three cases presented, conventional sinus x-rays were inadequate to detect sphenoid sinusitis. Delay in diagnosis increases morbidity and mortality from this infection. It is therefore advisable to expand the indications for CT scanning to include any patient with persistent severe headache, suspected as being of sinus origin, and symptoms of nasal stuffiness or purulent rhinorrhea, even when routine sinus films are normal.

Patients found to have opacification or an A-F level of the sphenoid sinus should be treated with IV antibiotics. If cultures are not available, high dose penicillinase-resistant penicillin is the drug of choice; and if symptoms persist, or if neurologic signs develop after initial antibiotic treatment, the sinus should be surgically drained. □

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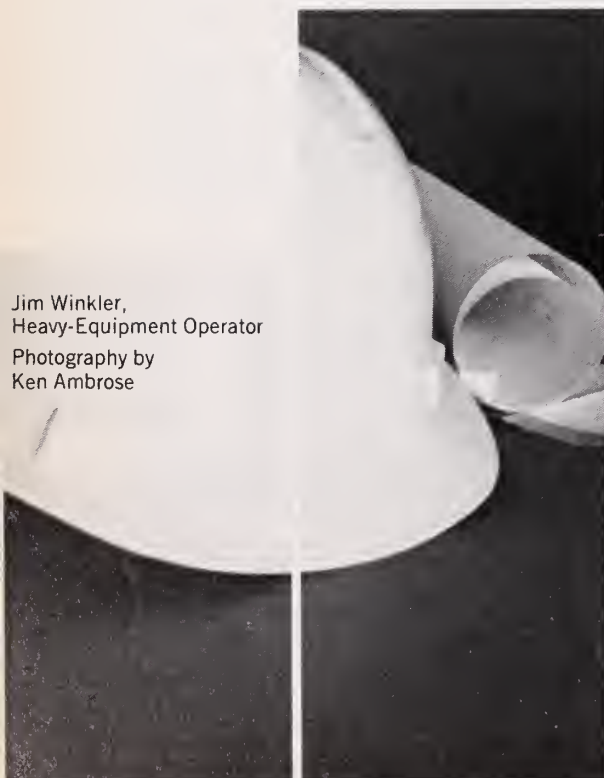
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AUXILIARY



*Mrs. Lamar Thomas
A-MASA President*

Awareness: Auxilians in Action

As we complete our 65th year as the Auxiliary to the Medical Association of the State of Alabama we can look back with a feeling of accomplishment as we have pursued many projects that have helped achieve better health for Alabamians.

We have made a concerted effort to help improve the image of medicine in Alabama through individual and collective work done within our communities. Spouses of physicians continue to work as volunteers in schools, hospitals and agencies that minister to the needs of the elderly, hungry, homeless, abused and neglected victims of our communities.

In keeping with our goal to make our members aware of timely medical issues one of our programs at the Fall Workshop was on AIDS. Dr. Claude E. Fox, State Health Officer, spoke on "Alabama Looks at AIDS" and Sara Muelling, technical director of the Red Cross Lab in Montgomery, reported on "AIDS and Blood

Banks." Brochures on AIDS were distributed to the counties to be used in their awareness campaign.

Auxiliaries have continued efforts to implement the child restraint safety bill by continuing with car seat loaner programs. The AMA developed a new program in conjunction with a major car manufacturer to educate the public on proper seat belt usage especially for pregnant women. This excellent program and brochure were widely shown throughout the state by county auxiliaries.

November was Alzheimer's Disease Awareness month. Many auxiliaries had programs which addressed this growing and pervasive problem that strikes a large percentage of our state's elderly. Brochures obtained from the Alzheimer's Disease Research Center were distributed by auxilians in their communities.

Mrs. Gaston McGinnis of Anniston, an auxilian actively involved with Alzheimer's caregivers support

group in her county, spoke to us at our Fall Workshop on "Alzheimer's and the Family."

Our largest fund-raising effort statewide this year as in years past has been for AMA-ERF. We appreciate the unfailing cooperation of Alabama physicians in these efforts which directly benefit our Alabama medical schools and medical students.

At this writing we do not have our final total for the year, but expect it to exceed last year's. We appreciate the enthusiastic efforts of our chairman, Mrs. Charles Patterson. Under her leadership "Apple A-Peel," a collection of apple recipes from auxiliaries, has been distributed throughout the state with sales to benefit AMA-ERF.

They will be on sale at our convention for \$7 each. Checks may be made to A-MASA Cookbook with \$5 for AMA-ERF tax-deductible. They may also be purchased from auxiliaries in your county. Sharing cards and holiday cards have continued to grow as have memorials and contributions. We are excited about our AMA-ERF involvement this year.

Our legislative chairmen have continued to keep us current with legislative issues of interest to the medical community. The swarm of activity prior to tort reform passage has continued to make auxiliary membership important to spouses of physicians.

We continue to support the work begun in Guatemala by Dr. and Mrs. Art Stamler by helping meet physical needs of the hospital as well as helping to establish an auxiliary for the spouses of their physicians. Mrs. Stamler reported to us on the progress made in a nursing home for the elderly after her last visit. We were delighted to make a contribution again toward this endeavor.

Much of the growth of our auxiliary is due to the excellent training provided by the AMA Auxiliary in Chicago each year. Leadership Confluence equips both state and county presidents-elect with the necessary knowledge to plan, lead and achieve auxiliary goals. Three days of lectures by experts in their fields is time and money well spent.

The enthusiasm of Chicago is carried back to county auxiliaries all across America. Internal auxiliary issues

were addressed, such as membership, finances and programs. Communication skills, such as listening, speaking and writing, were also included. Leaders from the AMA, AMA President Dr. William Hotchkiss, presented medical issues of today. We also heard about AIDS, Adolescent Health, Community Action Against Smoking and Family Stress During Malpractice Litigation.

Those in attendance in addition to the president were: A-MASA President-elect, Mrs. Robert Rhyne and nominated President-elect, Mrs. John Hardiman and county President-elect, Mrs. Charles Giddens, Jackson County; Mrs. George Eisenhart, Jefferson County; Mrs. Frank Hatchett, Lauderdale County; Mrs. Thomas Griggs, Madison County; Mrs. John LaFleur, Mobile County; Mrs. David Thrasher, Montgomery-Autauga County; Mrs. Gerry Ellis, Morgan-Lawrence County and Mrs. Michael Ursic, Tuscaloosa-Hale County.

We were proud to take an exhibit from Mobile County, Camp Rap-a-Hope, a camp for children with cancer, for our state's contribution to the project exchange between states that is a vital part of this meeting.

I would like to express the appreciation of the auxiliary to MASA's staff for their untiring assistance to our needs this year and to MASA for the support we have felt from you as we have strived toward mutual goals.

As our 1987-88 auxiliary year draws to a close I extend to all of you my heartfelt gratitude for all the gestures of friendship and encouragement, as well as all the apples, you have bestowed upon me as I traveled to visit the counties this past year.

May I introduce your new 1988-89 president, Mrs. Robert Rhyne of Moulton, who will assume office at the annual convention.

Marlynn is a very capable and energetic auxiliary who I know will sustain the high ideals of the medical auxiliary. □

Carole

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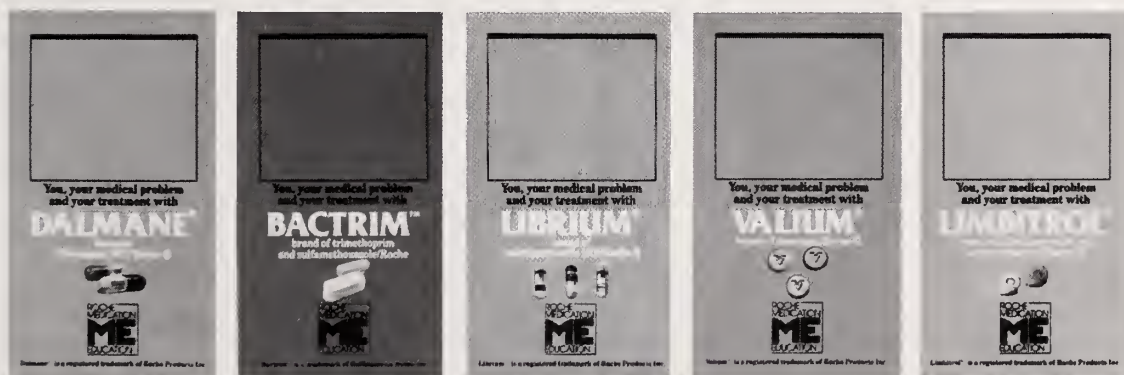


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Cover

In his inaugural presidential column on page 7, William A. Leitner, M.D., proposes that physicians rededicate themselves to patient-oriented care, thus to revitalize the most powerful lobby U.S. physicians can ever achieve — millions of Americans fully satisfied with their doctor. The cover symbolizes the purse-tightening of third-party payors, in government as well as the private sector, constrictions that adversely affect patients as well as physicians. Dr. Leitner counsels.

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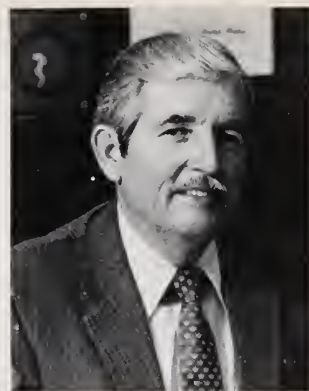
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S. Lon Conner
Executive Director, MASA

Dr. Holmes on Pseudo-Sciences

In March a federal jury in Cincinnati handed down an anti-trust verdict that rocked virtually every HMO in the country.

After four months of trial and a week of deliberation, the jury found that ChoiceCare, the biggest game in town, had conspired to fix prices, had engaged in securities fraud and racketeering, and had created a monopoly.

The \$34 million in damages, which would be tripled to \$102 million if the verdict is upheld, would go to the 1,800 present and former physician providers of ChoiceCare who brought the class action.

Since I am not a lawyer I can only pass on the judgment of those learned in the law that this is a barn-burner of a case, one that challenges many of the major assumptions of alternative care systems. In non-legal terms it means that 12 laymen found the HMO guilty of just about every kind of hanky-panky imaginable and dealt swift justice accordingly.

The case interested me because in it there seem to come together many of the phony arguments and posturing of those who claim to have invented a spectacular improvement over traditional fee-for-service medicine. Between government and sundry efforts in the private sector there has arisen a cherished notion that free and independent American physicians were hopelessly overmatched in trying to deliver health care economically and efficiently.

Almost overnight, swarms of self-certified experts descended on the medical marketplace, sustained by the belief that they could save the public money and

deliver health care better and more efficiently than a nation of bungling cottage industries, as they described the physicians who had made American health a model for the world.

Economics of scale, they said, would solve everything. Patients, employers, physicians, the general public — all would share in the bountiful free lunch so created. And, not incidentally, the facility would itself be in clover.

All the HMO failures and disasters of the past year or so have given pause to those who at first believed these disciples of the new medical economics. Employers who pay the bills are now demanding to know where the savings are — a question rendered somewhat more pressing by a related question about the dissatisfactions of the work force.

As Dr. Leitner pointed out in an interview published in *Alabama Medicine* last month, administrative expenses have gone through the roof, vaporizing those vaunted economies of scale. Dr. Leitner made the cogent observation that American business and industry have concluded that smaller operating units are often more efficient than giant systems, that there is a consequent trend in much of industry away from the very kind of bigness that HMOs claim is the solution.

What has deluded many investors, employers and patients alike, is a kind of pseudo-science of the medical economies.

In the last century, the great physician and premier literary figure, Oliver Wendell Holmes (1809-1894), had this to say on the subject of pseudo-science, and

he might well have been talking about the current fad for fiddling with health care delivery:

"I shall begin, my friends, with the definition of a pseudo-science. A pseudo-science consists of a *nomenclature* with a self-adjusting arrangement, by which all positive evidence, or such as favors its doctrines, is admitted, and all negative evidence, or such as tells against it, is excluded.

"It is invariably connected with some lucrative practical application. Its professors and practitioners are usually shrewd people; they are very serious with the public, but wink and laugh a good deal among themselves.

"The believing multitude consists of women of both sexes, feeble-minded inquirers, poetical optimists, people who always get cheated in buying horses, philanthropists who insist on hurrying up the millennium, and others of this class, with here and there a clergyman, less frequently a lawyer, very rarely a physician, and almost never a horse-jockey or a member of the detective police. . . .

"A pseudo-science does not necessarily consist wholly of lies. It may contain many truths, and even valuable ones. . . . The practitioners of the pseudo-science know that common minds, after they have been baited with a real fact or two will jump at the merest rag of a lie, or even at the bare hook.

"When we have one fact found for us, we are very apt to supply the next out of our own imagination."

Dr. Holmes had the uncanny Nostradamus gift for seeing the 20th Century from the vantage point of the 19th. Read the above again and I think you will agree he could have been talking about the pseudo-science of computerized diagnostics and other high-tech cookbook gibberish when he spoke, for example, of nomenclature.

What is finally dawning on the public is the central, underlying but always denied truth — that all the contraptions for collectivizing American medicine have, at bottom, beneath all the fancy labeling and tensil, a common, central purpose: the rationing of care.

What is now emerging, it seems to me, is that most of the rationers don't even do *that* very efficiently. ■

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Yohimbine exerts a stimulating action on the mood and may increase anxiety. Such actions have not been adequately studied or related to dosage although they appear to require high doses of the drug. Yohimbine has a mild anti-diuretic action, probably via stimulation of hypothalamic centers and release of posterior pituitary hormone.

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Contraindications: Renal diseases, and patient's sensitive to the drug. In view of the limited and inadequate information at hand, no precise tabulation can be offered of additional contraindications.

Warning: Generally, this drug is not proposed for use in females and certainly must not be used during pregnancy. Neither is this drug proposed for use in pediatric, geriatric or cardio-renal patients with gastric or duodenal ulcer history. Nor should it be used in conjunction with mood-modifying drugs such as antidepressants, or in psychiatric patients in general.

Adverse Reactions: Yohimbine readily penetrates the (CNS) and produces a complex pattern of responses in lower doses than required to produce peripheral a-adrenergic blockade. These include, anti-diuresis, a general picture of central excitation including elevation of blood pressure and heart rate, increased motor activity, irritability and tremor. Sweating, nausea and vomiting are common after parenteral administration of the drug.^{1,2} Also dizziness, headache, skin flushing reported when used orally.^{1,3}

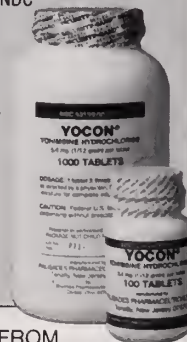
Dosage and Administration: Experimental dosage reported in treatment of erectile impotence.^{1,3,4} 1 tablet (5.4 mg) 3 times a day, to adult males taken orally. Occasional side effects reported with this dosage are nausea, dizziness or nervousness. In the event of side effects dosage to be reduced to 1/2 tablet 3 times a day, followed by gradual increases to 1 tablet 3 times a day. Reported therapy not more than 10 weeks.³

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References:

1. A. Morales et al., New England Journal of Medicine: 1221. November 12, 1981.
2. Goodman, Gilman — The Pharmacological basis of Therapeutics 6th ed., p. 176-188. McMillan December Rev. 1/85.
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4. A. Morales et al., The Journal of Urology 128: 45-47, 1982.

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William A. Leitner, M.D.
President, MASA

An Unbeatable Lobby

Dr. Carl Grote's year as my presidential predecessor was such a superlative performance that I am doubly humbled — first, to have been elected by you as your 1988-89 president, and secondly to accept the torch passed by him after such a great year.

I intend to devote the first part of my year to persuading Alabama physicians that:

(1) Our conventional lobbying efforts before Congress, although successful for decades, have been weakened, by a variety of social developments, to the point of impotency; similarly, third party payors no longer seem to care what we think.

But (2) by rededicating our efforts to patient-oriented care, by doing what we should have been doing all along or doing it even better, we can effectively mobilize the greatest lobby of them all — the electorate.

By the last I mean that our patients will do our lobbying for us if they are completely satisfied with the medical care they receive. At the moment, many of them are thoroughly perplexed by the turbulence in the medical marketplace, by alternative systems, and by all manner of purse-tightening by the third-party payors, government as well as private sector.

For years they, like us, took the conventional delivery systems pretty much for granted. Now they are confused, but in their confusion they are increasingly sensitive to value received. It is the responsibility, and the opportunity, of the American physician to return

to the way it was before the disruptions of recent years — to return to the transcendent importance of the patient, first, last and always.

At the risk of appearing to overgeneralize, I believe it fair to say that there has been a tendency in recent years to divert too much of our energy and attention to the business side of practice. The number of hours in a day being finite, it was perhaps inevitable that patients lost some of their premier importance because of our preoccupation with the shifting ground beneath our feet.

To the extent that this *has* occurred, we are placing at risk the greatest resource we have always had to preserve practice freedom — public opinion, which means patient opinion. And that is formed, I believe, not by all the bureaucratic position papers, not by the punditry of the media, not by the caterwauling of politicians, but by the private, personal experiences of individual Americans. If they are pleased and satisfied with their doctors, these individual judgments swell into a powerful aggregate that forms the national consensus.

Organized medicine's formal lobbies in Washington have been checkmated in recent years by the vast constellation of consumer lobbies, ranging from the trivial to the awesome: AARP has close to 30 million members and an annual budget of \$100 million.

To every lobby in Washington, it has been said, there is now at least one equal but opposite lobby,

with the result that a kind of impasse has been reached in the corridors of the Capitol.

For good or ill, and I regard it as generally good, this returns the battle for public opinion to where it was before the armies of special interests descended on Washington — to the public, in the towns, cities and countryside of the land.

No other interest group has the daily contact physicians do with the millions of citizens who form that "public opinion."

Ralph Nader doesn't exist in our offices and the likes of Teddy Kennedy are as Martians. In the final analysis, since the competing Washington lobbies frequently cancel each other out, legislation is determined by what the folks back home want. If only by default, the Republic has reinvented the wheel. The people have regained their voice and power.

These homefolks are our patients. When we treat them with dignity and respect; when we help lead them through the bewildering maze of insurance and other personal anxieties that are part of their total well-being, which should be our first concern, we are practicing good medicine. But we are also mobilizing our lobby of the entire American electorate. We have been reluctant in the past to carry out this type of activity.

But we should remember that as long as our efforts are in the patient's interest, there is no conflict.

Equally true, of course, is the reverse — when we leave patients disappointed or even angered by the service they receive from their doctors, we are lobbying for those who would, if they could, destroy private practice.

What I propose is anything but revolutionary. Simply put, it is to return to patient-oriented care with all the enthusiasm of both good medical practice and good politics, knowing they are one and the same.

In fact, this happy conjunction of physician interests — unexceptionable care and pragmatic politics — may well be one of the few genuine silver linings in all those dark clouds.

I'll have more specifics on this subject as the year progresses. Thank you for the honor of serving as your president. □

Bill

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Table adapted from Facts and Comparisons (Nov.) 1984 and Catalano RB. The medical approach to management of pain caused by cancer. "Semin Oncol" 1975, 2; 379-92 and Reuler JB, et. al. The chronic pain syndrome: misconceptions and management. "Ann Intern Med" 1980; 93; 588-96.

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PRECAUTIONS:

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Information for Patients: VICODIN, like all narcotics, may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery; patients should be cautioned accordingly.

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Nursing Mothers: It is not known whether this drug is excreted in human milk; therefore, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS:

Central Nervous System: Sedation, drowsiness, mental clouding, lethargy, impairment of mental and physical performance, anxiety, fear, dysphoria, dizziness, psychic dependence, mood changes.

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Revised, April 1982.

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2. Beaver, WT *Arch Intern Med*, 141:293-300, 1981.

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Medical Practice a la Mode*

How Medical Fashions Determine Medical Care

John F. Burnum, M.D.†

That I might be a pawn of fashion first came home to me about 10 years ago when a number of new nonsteroidal antiinflammatory drugs were being introduced. In October 1978, sulindac (Clinoril) was introduced to the market and to the public in a press conference that resulted in extensive media coverage. Within a few hours of the first press reports, I was buried by an avalanche of urgent telephone requests for the new wonder drug. With ill humor, I complied. No credit to me that sulindac turned out to be a useful drug; I was merely kneeling to fashion. Benoxaprofen (Oraflex) was next to become all the rage for arthritis. I decided to resist. How foolish; my patients simply called a willing competitor. That benoxaprofen was almost simultaneously withdrawn from the market because of dangerous side effects has no bearing on the lesson: What is new is best, and one must stay in vogue. When members of the staff of the hospital's intensive care unit smiled patiently because I did not order the latest cephalosporin, my paranoia was complete. I should have heeded Colley Cibber, who said, in the 17th century, "one had as good be out of the world as out of the fashion."¹ Subsequently, to my chagrin, I noted that a number of other drugs were often dispensed à la mode.

Treatments of Fashion

But take heart; we are in good company. The imperative to be stylish affects the brightest and the best. Despite there being no change in the type of pneumonia they were encountering, the house staff at Johns Hopkins often treated community-acquired pneumonia with multiple-drug therapy involving cephalosporins and aminoglycosides when ordinary penicillin would have sufficed.² This should not have surprised me, because physicians tend to pick up their prescribing habits more

from one another than from the scientific literature³; giving a new drug spreads as a contagion from one physician in the medical community to another, and thus a fashion is born.

Fashion has been sporting with me for years. It has long fascinated me that in our area we carefully prescribe Atarax for itching and Vistaril for nausea, although they are the same drug (hydroxyzine). Why? Because of tradition and fashion, I would think. Likewise, we give diazepam three times a day; logically, because of its long half-life, it should be given only once a day. Although they are of equal value, we choose methylprednisolone over dexamethasone in septic shock.⁴ That propoxyphene is far more expensive than acetylsalicylic acid and no better an analgesic is irrelevant: propoxyphene is "in."

Some traditional fashions are under attack. Orange juice may not be the best treatment for insulin reactions⁵; the efficacy of digitalis in congestive heart failure without atrial fibrillation and an S3 gallop is unproved; and ergoloid mesylates, the 11th most commonly prescribed drug in the world, is of doubtful benefit in senile dementia,⁶ as are vasodilators.

On top of all that, instead of having our patients eat white Vaseline for diverticulitis, we have made a 180-degree turn, and now recommend roughage and fiber. Is nothing sacred anymore? In the spirit of Stephen Potter, the games doctor learns to sit out these controversies and await the movement of the herd. In the meantime, he knows that worse than prescribing out of style would be prescribing nothing at all.

Fashions in Medical Science

Fashion also has a say in the directions of medical science. Laboratory tests have their day in the sun. When I was in training, all patients had to have an eosinophil count; later, they required a test for Hargraves lupus cells. Now the bone densitometer test for osteoporosis is riding the wave of fashion⁷; probably,

* Reprinted from the *New England Journal of Medicine* 317:1220-1222 (November 5), 1987.

† Tuscaloosa, AL.

it too will pass. Research is much the same. The research-grant gamesman knows that yesterday's darling is today's stepchild; better to go for aging studies than circulatory physiology.

Some scientific questions seem to pulse in and out of fashion. Our flare of interest in cholesterol in the 1950s soon died, but returned in the 1980s as Barr's⁸ earlier warnings about beta-lipoproteins bore fruit. In the 1940s Addis supplied evidence of the value of limiting protein in renal failure; in 1981 Brenner's group did the same.⁹ This is not to disparage the important work of the recent investigators. I am merely reflecting on my sense of *déjà vu*. Stress is another example of a pulsating scientific issue. In the 1930s it was Cannon's "fight or flight,"¹⁰ in the 1950s Selye's alarm reaction,¹¹ in 1974 Friedman's Type A personality,¹² and in 1984 Eliot's hot reactor.¹³ Belief in stress as a cause of disease is currently on the wane.

Diseases of Fashion

Diseases of fashion exert a strong influence on medical practice — on what we and the public think about disease and what is treated. These are conditions that epidemically gain the medical limelight and in their time receive an inordinate amount of media and public attention. In the 1930s people were afflicted wholesale by "an acid condition," and in the 1940s by a lack of acid, which we treated with hydrochloric acid. Hypoglycemia soon swept the country and continues to ebb and flow in popularity. Chronic mononucleosis had its day and is currently having a scientific renaissance. Mitral-valve prolapse has caught the public's fancy and has been the answer to many a doctor's prayer as a catchall explanation for a number of frustrating complaints; DaCosta's 1871 paper¹⁴ caught our attention none too soon. The temporomandibular joint syndrome was next, followed quickly by the premenstrual and post-traumatic stress syndromes, osteoporosis, fibromyositis, and the candidiasis hypersensitivity syndrome (a disorder in scientific limbo). And on they go, from one disease of the month and one disease of fashion to another.

Please note that in no way am I making fun of patients' fears or the gravity of some of these disorders. What I am saying is that we are predisposed to diagnose, and our patients to worry about, the diseases that are in the news, popularized, and impressed on our minds. As an accompanying phenomenon, entrepreneurial specialists in and clinics for the various bandwagon diseases often spring up to capitalize on medical chic; for example, whether scientifically justified or not, hundreds of osteoporosis clinics are in the offing.⁷ Cousins to diseases of fashion are media-sown disease panics; for example, fear of saccharin, of reserpine, or of coffee's causing cancer, or an obsessional dread of having colon cancer, the acquired

immuno-deficiency syndrome, or Alzheimer's disease.

Cultural Diseases and Treatments of Fashion

There are many cultural diseases and treatments of fashion that contribute heavily to the content of medical care. In my area, patients may have "bilious attacks" or "low blood"; among Mexican Americans it may be *susto*. In the Alps the hot wind from the south, the *foehne*, is particularly noxious and causes all sorts of bad feelings and behavior. In France, the treatment of *crise de foie*, an illness declared to be nonexistent, accounts for 5 percent of the total drug consumption in the country. Myth or not, the fashion-minded doctor is ready to treat it. We practitioners have to be nimble to keep up with the capricious changes in folk-medicine vogues. For example, sea water for arthritis is old-fashioned, bee pollen has been replaced by alfalfa tea, which in turn is being dethroned by aloe, and copper bracelets and buckeye amulets have never gone away.

Keeping up with fashions in nutrition and physical fitness is beyond me. No sooner had I mastered Adele Davis' teachings than my patients had gone on to the Last-Chance Diet. Now it is the Rotation Diet, and there were so many before that I have lost track. By the time I learned the Air Force exercises, my patients had long since switched to the Jane Fonda workouts. Who am I to point to anemia, amenorrhea, and osteoporosis in joggers, or to complain that nearly 40 percent of the population wastes money on vitamins? Who am I to say that healthy people do not need special organic foods? I surrender; as long as my patients avoid polar bear liver and vitamin A poisoning, why not acquiesce and stay in style? In the areas of nutrition and physical fitness, fashion and fads run amok and almost completely dictate medical care.¹⁵

Fashions in Surgery

Nor can surgery claim independence from fashion. Freezing the stomach for peptic ulcer disease, implanting the mammary artery for ischemic heart disease, and inflating a gastric balloon for obesity are humbling examples of fashionable treatments of no benefit. The corrected rates at which surgical procedures are performed vary beyond reason from one comparable part of the country to another (nearly fourfold for hysterectomies). Wennberg suggests that these discrepancies may represent differences in practice styles.¹⁶

Conclusion

Medical fashions have a powerful effect on how we treat, whom we treat, and what we treat, on how patients take care of themselves, and even on the directions of medical science. It shames me to admit that

continued on page 14



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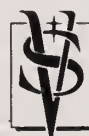
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Medical Fashions

continued from page 12

I have given fashion a say in my treatment of patients. Consider the irony: as professed scientists and proponents of Cartesian doubt, we physicians find ourselves, like lemmings, episodically and with a blind infectious enthusiasm pushing certain diseases and treatments primarily because everyone else is doing the same. This is unacceptable. Kowtowing to fashion gives the lie to our intellectual integrity and may result in medical care that is not scientifically justified and in decisions that are not in the best interests of our patients. All fashions in medical care are not necessarily harmful and to be condemned, but all are suspect.

Escaping the lure of pop medicine and the herd syndrome will not be easy, for fashion is a seductive and powerful foe. It offers the warmth and reassurance that come with being in a group and acting in unity. It supplies ready, painless answers; hard thinking and critical doubt are no longer required. And, at a time of shrinking medical income, the exploitation of medical fashions offers a rich opportunity for financial gain. The lines are drawn. Which shall it be, science or fashion? Let each decide. □

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WARNINGS: **FATALITIES ASSOCIATED WITH THE ADMINISTRATION OF SULFONAMIDES, ALTHOUGH RARE, HAVE OCCURRED DUE TO SEVERE REACTIONS, INCLUDING STEVENS-JOHNSON SYNDROME, TOXIC EPIDERMAL NECROLYSIS, FULMINANT HEPATIC NECROSIS, AGRANULOCYTOSIS, APLASTIC ANEMIA AND OTHER BLOOD DYSCRASIAS.**

BACTRIM SHOULD BE DISCONTINUED AT THE FIRST APPEARANCE OF SKIN RASH OR ANY SIGN OF ADVERSE REACTION. Clinical signs, such as rash, sore throat, fever, arthralgia, cough, shortness of breath, pallor, purpura or jaundice, may be early indications of serious reactions. In rare instances a skin rash may be followed by more severe reactions, such as Stevens-Johnson syndrome, toxic epidermal necrolysis, hepatic necrosis or serious blood disorder. Perform complete blood counts frequently. **BACTRIM SHOULD NOT BE USED IN THE TREATMENT OF STREPTOCOCCAL PHARYNGITIS.** Clinical studies show that patients with group A B-hemolytic streptococcal tonsillopharyngitis have a greater incidence of bacteriologic failure when treated with Bactrim than with penicillin.

PRECAUTIONS: *General:* Give with caution to patients with impaired renal or hepatic function, possible folate deficiency (e.g., elderly, chronic alcoholics, patients on anticonvulsants, with malabsorption syndrome, or in malnutrition states) and severe allergies or bronchial asthma. In glucose-6-phosphate dehydrogenase deficient individuals, hemolysis may occur, frequently dose-related.

Use in the Elderly: May be increased risk of severe adverse reactions in elderly, particularly with complicating conditions, e.g., impaired kidney and/or liver function, concomitant use of other drugs. Severe skin reactions, generalized bone marrow suppression (see WARNINGS and ADVERSE REACTIONS) or a specific decrease in platelets (with or without purpura) are most frequently reported severe adverse reactions in elderly. In those concurrently receiving certain diuretics, primarily thiazides, increased incidence of thrombocytopenia with purpura reported. Make appropriate dosage adjustments for patients with impaired kidney function (see DOSAGE AND ADMINISTRATION).

Use in the Treatment of Pneumocystis Carinii Pneumonia in Patients with Acquired Immunodeficiency Syndrome (AIDS): AIDS patients may not tolerate or respond to Bactrim in same manner as non-AIDS patients. Incidence of side effects, particularly rash, fever, leukopenia, elevated aminotransferase (transaminase) values, with Bactrim in AIDS patients treated for *Pneumocystis carinii* pneumonia reported to be greatly increased compared with incidence normally associated with Bactrim in non-AIDS patients.

Information for Patients: Instruct patients to maintain adequate fluid intake to prevent crystalluria and stone formation.

Laboratory Tests: Perform complete blood counts frequently, if a significant reduction in the count of any formed blood element is noted, discontinue Bactrim. Perform urinalyses with careful microscopic examination and renal function tests during therapy, particularly for patients with impaired renal function.

Drug Interactions: In elderly patients concurrently receiving certain diuretics, primarily thiazides, an increased incidence of thrombocytopenia with purpura has been reported. Bactrim may prolong the prothrombin time in patients who are receiving the anticoagulant warfarin. Keep this in mind when Bactrim is given to patients already on anticoagulant therapy and reassess coagulation time. Bactrim may inhibit the hepatic metabolism of phenytoin. Given at a common clinical dosage, it increased the phenytoin half-life by 39% and decreased the phenytoin metabolic clearance rate by 27%. When giving these drugs concurrently, be alert for possible excessive phenytoin effect. Sulfonamides can displace methotrexate from plasma protein binding sites, thus increasing free methotrexate concentrations.

Drug-Laboratory Test Interactions: Bactrim, specifically the trimethoprim component, can interfere with a serum methotrexate assay as determined by the competitive binding protein technique (CBPA) when a bacterial dihydrofolate reductase is used as the binding protein. No interference occurs if methotrexate is measured by a radioimmunoassay (RIA). The presence of trimethoprim and sulfamethoxazole may also interfere with the Jaffe alkaline picrate reaction assay for creatinine, resulting in overestimations of about 10% in the range of normal values.

Carcinogenesis, Mutagenesis, Impairment of Fertility: *Carcinogenesis:* Long-term studies in animals to evaluate carcinogenic potential not conducted with Bactrim. *Mutagenesis:* Bacterial mutagenic studies not performed with sulfamethoxazole and trimethoprim in combination. Trimethoprim demonstrated to be nonmutagenic in the Ames assay. No chromosomal damage observed in human leukocytes *in vitro* with sulfamethoxazole and trimethoprim alone or in combination; concentrations used exceeded blood levels of these compounds following therapy with Bactrim. Observations of leukocytes obtained from patients treated with Bactrim revealed no chromosomal abnormalities. *Impairment of Fertility:* No adverse effects on fertility or general reproductive performance observed in rats given oral dosages as high as 70 mg/kg/day trimethoprim plus 35 mg/kg/day sulfamethoxazole.

Pregnancy: *Fetal Toxic Effects:* Pregnancy Category C. Trimethoprim and sulfamethoxazole may interfere with folate metabolism; use during pregnancy only if potential benefit justifies potential risk to fetus. *Nonteratogenic Effects:* See CONTRAINDICATIONS section.

Nursing Mothers: See CONTRAINDICATIONS section.

Pediatric Use: Not recommended for infants under two months (see INDICATIONS and CONTRAINDICATIONS sections).

ADVERSE REACTIONS: Most common are gastrointestinal disturbances (nausea, vomiting, anorexia) and allergic skin reactions (such as rash and urticaria). **FATALITIES ASSOCIATED WITH THE ADMINISTRATION OF SULFONAMIDES, ALTHOUGH RARE, HAVE OCCURRED DUE TO SEVERE REACTIONS, INCLUDING STEVENS-JOHNSON SYNDROME, TOXIC EPIDERMAL NECROLYSIS, FULMINANT HEPATIC NECROSIS, AGRANULOCYTOSIS, APLASTIC ANEMIA AND OTHER BLOOD DYSCRASIAS (SEE WARNINGS SECTION).**

Hematologic: Agranulocytosis, aplastic anemia, thrombocytopenia, leukopenia, neutropenia, hemolytic anemia, megaloblastic anemia, hypoprothrombinemia, methemoglobinemia, eosinophilia. *Allergic Reactions:* Stevens-Johnson syndrome, toxic epidermal necrolysis, anaphylaxis, allergic myocarditis, erythema multiforme, exfoliative dermatitis, angioedema, drug fever, chills, Henoch-Schoenlein purpura, serum sickness-like syndrome, generalized allergic reactions, generalized skin eruptions, photosensitivity, conjunctival and scleral injection, pruritus, urticaria and rash. *Periarthritis nodosa* and systemic lupus erythematosus have been reported. *Gastrointestinal:* Hepatitis (including cholestatic jaundice and hepatic necrosis), elevation of serum transaminase and bilirubin, pseudomembranous enterocolitis, pancreatitis, stomatitis, glossitis, nausea, emesis, abdominal pain, diarrhea, anorexia. *Genitourinary:* Renal failure, interstitial nephritis, BUN and serum creatinine elevation, toxic nephrosis with oliguria and anuria, crystalluria. *Neurologic:* Aseptic meningitis, convulsions, peripheral neuritis, ataxia, vertigo, tinnitus, headache. *Psychiatric:* Hallucinations, depression, apathy, nervousness. *Endocrine:* Sulfonamides bear certain chemical similarities to some gonitogens, diuretics (acetazolamide and the thiazides) and oral hypoglycemic agents; cross-sensitivity may exist. Diuresis and hypoglycemia have occurred rarely in patients receiving sulfonamides. *Respiratory:* Pulmonary infiltrates. *Musculoskeletal:* Arthralgia, myalgia. *Miscellaneous:* Weakness, fatigue, insomnia.

DOSAGE AND ADMINISTRATION: Not recommended for use in infants less than two months of age. **URINARY TRACT INFECTIONS AND SHIGELLOSIS IN ADULTS AND CHILDREN, AND ACUTE OTITIS MEDIA IN CHILDREN:** Usual adult dosage for urinary tract infections is one DS tablet, two tablets or four teaspoonfuls (20 ml) b.i.d. for 10 to 14 days. Use identical daily dosage for 5 days for shigellosis. *Recommended dosage for children with urinary tract infections or acute otitis media* is 8 mg/kg trimethoprim and 40 mg/kg sulfamethoxazole per 24 hours, in two divided doses every 12 hours for 10 days. Use identical daily dosage for 5 days for shigellosis. *Renal Impaired:* Creatinine clearance above 30 ml/min, give usual dosage; 15-30 ml/min, give one-half the usual regimen, below 15 ml/min, use not recommended.

ACUTE EXACERBATIONS OF CHRONIC BRONCHITIS IN ADULTS: Usual adult dosage is one DS tablet, two tablets or four teasp (20 ml) b.i.d. for 14 days.

PNEUMOCYSTIS CARINII PNEUMONIA: Recommended dosage is 20 mg/kg trimethoprim and 100 mg/kg sulfamethoxazole per 24 hours in equal doses every 6 hours for 14 days. See complete product information for suggested children's dosage table.

HOW SUPPLIED: DS (double strength) Tablets (160 mg trimethoprim and 800 mg sulfamethoxazole)—bottles of 100, 250 and 500; Tel-E-Dose® packages of 100, Prescription Paks of 20, 40, 60, 80, 100, 120, 140, 160, 180, 200, 220, 240, 260, 280, 300, 320, 340, 360, 380, 400, 420, 440, 460, 480, 500, 520, 540, 560, 580, 600, 620, 640, 660, 680, 700, 720, 740, 760, 780, 800, 820, 840, 860, 880, 900, 920, 940, 960, 980, 1000; Suspension (40 mg trimethoprim and 200 mg sulfamethoxazole per teasp.)—bottles of 100 ml and 16 oz (1 pint). *Suspension* (40 mg trimethoprim and 200 mg sulfamethoxazole per teasp.)—bottles of 16 oz (1 pint).

STORE TABLETS AT 15°-30°C (59°-86°F) IN A DRY PLACE PROTECTED FROM LIGHT. STORE SUSPENSIONS AT 15°-30°C (59°-86°F) PROTECTED FROM LIGHT.

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CORRESPONDENCE

Voter's Dilemma

Dear Editor:

I have begun to read various letters and reports representing the position of physicians as such positions might relate to the upcoming election of five justices to the Alabama Supreme Court.

I have been troubled by the fact that I find my political, social, and economic views better represented by the Republican Party than the Democratic Party. It is my opinion that no justice will seek a seat on the Alabama Supreme Court as a Republican.

This means that for me to participate and to have weight in the election process, then I must participate as a Democrat. The only possible exception would be should there be a Democratic Party runoff and I switch in the runoff from Republican to Democrat. I trust that most readers of this letter can look at our Republican Governor and remember that he became governor by virtue of the switch voting just described.

It is my opinion that the Republican Party represents a substantial majority position taken by the membership of MASA. If the members of MASA participate in the Democratic primaries they will find that they have no influence in the Republican Party.

With the foregoing in mind, I would appreciate an explanation of how I can remain loyal to the Republican Party and at the same time have much weight with the Democratic Party's selection of Alabama Supreme Court justices?

It is my opinion that physicians have frequently surrendered their long term interest because of the heat of the local day. This schizophrenic type of behavior is one of the causes for the lack of political whammy so often seen today. Unless and until I am shown how I can be an effective Republican by participating in the Democratic primaries, then it is my intention to so not participate. I would like to hear from my colleagues as to their feelings on this point.

JOSEPH P. MUDD, JR., M.D.
 Jackson, Alabama

Treatment of Male Impotence — A Pharmacologic Erection Program

Carl J. Sanfelippo, M.D.*

Albert J. Tully, Jr., M.D.*

William A. Leitner, M.D.*

Cecil Morgan, Jr., M.D.*

A. M. Deason, Jr., M.D.*

Rodney L. Dennis, M.D.*

Chris Spivey, S.A.*

Becky Holmes, S.A.*

Robert T. Russell, M.D.*

Impotence is reported to affect at least 10 million men in the United States. The etiologies include hormonal deficiency, vascular abnormalities, neurologic deficits and psychological problems. Often there are multiple etiologies involved. As late as 1980, 90% of impotence problems were felt to be due to psychologic problems and only 10% due to organic disease. Now in 1987 with better diagnostic techniques we know that more than 50% of these problems are truly organic in nature.

Recently we have developed an organized approach to determine the extent of these above factors involved. We then use this information for a more logical treatment program to improve potency. One of the new treatments available is the use of penile injections to create an erection. This technique and our results will be discussed below.

Evaluation

All patients referred for potency difficulties undergo a detailed history and physical examination. A thorough history is the most important diagnostic tool, and in about 90% of the cases it will indicate the etiology involved. Hormonal screening studies include serum testosterone, prolactin, and LH. Nocturnal snap gauge testing helps to determine whether the patient is physically capable of normal erectile function. This is a good screening device for organic versus psychogenic impotence. Patients suspected of vascular abnormalities undergo penile doppler evaluation with determination of penile-brachial index (PBI).⁵ Biothesiometry is used to screen for neurologic abnormalities. Psychologic testing (MMPI) and nocturnal penile tumescence (NPT) studies are also done to screen for psychologic problems especially in younger patients.

This battery of testing will enable us to determine the causative factors and plan a treatment course for the patient. Not all of the above tests are appropriate or necessary for all patients.

*Urology Associates, P.C., 1000 South 14th St., Birmingham, AL 35205.

Treatment

Treatment options in the past have included the following:

1. Supplemental testosterone — Only given to patients with low serum testosterone levels. Testosterone primarily affects libido and not erectile function directly and its long term use in patients with otherwise normal testosterone production may produce deleterious side effects.

2. Yohimbine — An oral alpha 2 adrenergic blocking agent which may increase penile blood flow.

3. Isoxsuprine hydrochloride — An oral peripheral vasodilator which may increase penile blood flow.

4. Vacuum device — This induces penile engorgement through vacuum suction and maintains erection by a constricting band.¹

5. Psychological counseling — For those patients where an organic abnormality has been ruled out.

6. Penile prosthesis — A surgical implant is reserved for those patients who are unable to be helped with above medical therapy.

In the early 1980's Virag initiated a program of intracavernous self-injection of a vaso-active substance that was able to create an erection.² A combination of papaverine and phentolamine is now used for its diagnostic and therapeutic properties.³ Papaverine relaxes the smooth musculature of the arteries and lacunae of the corpora cavernosa. Phentolamine is an alpha adrenergic blocking agent and together these drugs result in penile vascular engorgement and an erection. Papaverine hydrochloride (30 mgs. per ml.) and phentolamine mesylate (1 mg. per ml.) are used in varying amounts. The drugs are injected with a 28 or 30 gauge needle into one of the corpora cavernosum near the base of the penis as shown in Figure 1.

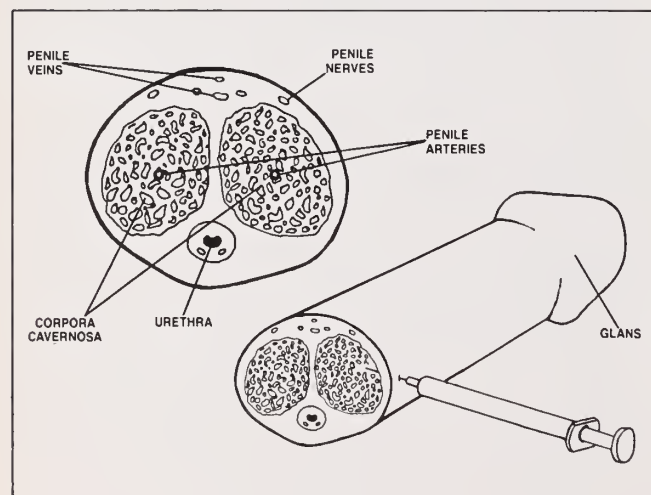


Figure 1. Cross-section view of penile shaft shows the relationship of the urethra to the corpora cavernosa. Longitudinal view shows injection of corpora from lateral aspect.

As a diagnostic agent, papaverine alone in very small doses will cause an erection in psychologic impotence and thus help to define and direct that patient to appropriate counseling.

For those patients with organic (non-psychologic) impotence who have not responded to or declined other forms of treatment the papaverine-phentolamine injections may be therapeutic. The following protocol is used: injections are initially done in the office. Since the dosage to achieve full erection is quite variable from patient to patient, we start out by injecting the smallest amount (0.1 cc.) of the mixture and if this does not cause satisfactory erections the patient returns in one week and the dosage is increased by incremental amounts until satisfactory erection results and remains for 30 to 60 minutes. If the maximum dosage (2 ccs.) does not provide an erection, this indicates severe vascular disease (arterial insufficiency or venous leakage) and the program cannot be used for this individual patient. If an erection occurs the patient remains in the office and is monitored every fifteen minutes until the erection subsides. Prolonged erections can be detrimental to the vascular tissue in the corpora and therefore if an erection persists longer than four hours, the corpora are irrigated with a dilute solution of neosynephrine or epinephrine until detumescence occurs. Once the optimum dosage for that particular patient is arrived at, the patient himself learns the technique of drawing up the exact volume of medication and proper injection technique. The patient is given a two month's supply (up to ten injections per month may be used) and is allowed to use the medication for sexual relations at home.

The injection technique may fail to work in approximately 30% of the patients, usually because of advanced penile vascular disease and for these patients, consideration of a penile prosthesis may be appropriate.⁴

Results

From May, 1985, through December, 1986, 225 patients with impotence were evaluated and/or treated with papaverine-phentolamine injections.

Our patients ranged in age from 20 to 84 with 56% being age 60 or above (see Table 1). The vast majority (188/225 or 83.6%) of the patients had vascular abnormalities causing their impotence (see Table 2). These patients have been classified into two groups: those that are receiving home therapy and those who received office injections only.

Home Therapy: Papaverine-phentolamine injections at home as definitive therapy were offered to 123 patients. 89/123 (72%) are continuing to use this as therapy for their impotence without problems or complications. 16/123 (13%) did not continue to have sufficient erections for intercourse with the injections

TABLE 1
Age Distribution of Patients

Age	Number
Less than 30	4
31-40	11
41-50	32
51-62	57
61 or greater	121
Total	225

and 5 (4.1%) of these elected to have a penile prosthesis. 4/123 (3.3%) patients developed better erections after initial injection therapy and no longer needed any therapy for satisfactory relations. Whether this is due to improved and sustained blood flow, psychologic benefit, or some other phenomenon is not completely understood but has been reported from other sources. 12/123 (9.8%) patients have discontinued the program because of personal reasons.

Office Only: 102/225 (45.3%) patients had office injections only and did not utilize home injection therapy. Of these 55/102 (53.9%) had no significant response to the injections even at a maximum dosage and elected other treatment modalities. 10/55 (18.2%) proceeded to a penile prosthesis. 8/102 (7.8%) patients had injections for diagnostic purposes only (to help differentiate psychologic from organic impotence). 34/102 (33.3%) noted significant improvement in erections after multiple office injections and did not need any more injections to attain satisfactory relations at home. Again, this benefit may be partly psychologic, partly improved blood flow, or some other unknown mechanism.

Follow-up and Complications

Once home therapy has been initiated, patients are followed at two month intervals. They are examined for injection site injuries or evidence of corporal fibrosis. Although this has been reported in a small percentage of patients by other groups, we have not yet seen these problems.⁶ Prolonged erections (priapism) have occurred in 10% of patients with initial office injections. All of these have been easily managed with in-office irrigations. Home therapy priapism requiring emergency room irrigation has occurred in only one patient. The small incidence of problems is due to precise training of the patient in the office prior to initiating home therapy.

Conclusions

The use of self-injection papaverine-phentolamine has proved to be a significant treatment for erectile dysfunction. 89/123 (72%) of the patients on home

TABLE 2
Etiology of Erectile Dysfunction

Vascular	188
Diabetic	25
Neurogenic	24
Post-Surgical	5
Psychogenic	10
Total	254*

*Includes multiple etiologies

injection therapy continue to use the method and are pleased with the results. For these patients, the injection therapy will allow them to have successful relations without necessarily proceeding to a penile prosthesis. Reviewing both groups (office injection only and home therapy) the papaverine-phentolamine injections were unable to provide adequate erections in 71/225 (31%).

The advantage of this new program is that it aids in diagnosis and it provides another treatment option to patients with organic impotence. It may also be used in psychogenic impotence but concomitant psychologic counseling should be undertaken. The long term affects are still unknown but in a carefully supervised program these are anticipated to be minimal.

The Future

In the last five years we have learned a great deal about the causes and treatment of impotence. We have learned that many of the patients that we thought had psychogenic impotence truly do have organic problems that can be corrected or improved.

Considerable research is now being conducted in the field of arterial revascularization procedures and ligation of venous leaks in those patients with vascular impotence. Simpler and better prosthetic devices continue to be produced each year. Until the ultimate procedure or device is defined, this pharmacologic erection program will continue to play a major role in the modern diagnosis and treatment of impotence. □

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The Future of American Medicine

William L. Roper, M.D.*
Administrator, Health Care Financing Administration

I am pleased to return to my home town, and to my alma mater, to discuss the present and future of American medicine. So much has changed lately that we are used to discussing the "revolution" in health care. This is a cliché, but one that is nonetheless true. I believe it is worthwhile to step back and take the long view of where we are going.

When it comes to the Health Care Financing Administration, I know that everyone recognizes the importance of our running the nation's Medicare program in a way that assures health care that is not only accessible and affordable, but also of the highest quality.

Yet despite our agreement, in all honesty, there must be times — perhaps when we issue still another regulation, or reporting requirement — when HCFA threatens to become everyone's favorite four-letter word.

Simply because we all admit that the Federal government has a bona fide role to play does not mean we should accept without question that it is now playing the proper role.

With that in mind, I would like this afternoon to discuss two very important issues.

First, I want to amplify on HCFA's role in measuring quality care, detailing for you the story behind our recent release of hospital mortality information, and telling you something about our thoughts on measuring the effectiveness of care.

Then, I would like to broaden the discussion, to consider some of the problems with the current Federal micromanagement of health policy, as well as some suggestions for a more competitive health care system.

Mortality Information

By nominating me to be the Administrator of HCFA, President Reagan in essence put me in charge of the nation's largest health-care quality assurance program. And "quality is our most important product."

I quickly came to believe that the best way to meet this charge was to gain a better understanding of just what quality means, how to measure it, how to control for it and how to enhance it.

This mandate was made more urgent by the fact that just shortly before I took office, Medicare for the first time had released information on the mortality rates at the nation's acute-care hospitals.

This information release was intended for the use of PROs conducting review of care provided to Medicare patients. We clearly stated that the lists did not necessarily indicate good or bad providers.

But we learned from our experience that the hospital

* An address to the Alumni Association, University of Alabama, School of Medicine, Birmingham, AL, February 20, 1988.

and medical communities needed to play a much larger role in such an effort. And more needed to be done to communicate how such information should be interpreted and used.

That is why, in December 1986, HCFA convened a quality of care symposium which included professionals from consumer groups, providers and academia.

We subsequently had technical consultations with nationally recognized experts in health and statistics. We spoke with major health care and consumer organizations, as well as with the public.

Once we had decided on our plans, we went to great lengths to be clear. Workshops were held in early December at which the news media and various groups, including the AMA, were invited. At these workshops, we discussed the format of the information about to be released, methods of interpretation, and proper caveats about its use.

Then, on December 17, HCFA released its information on mortality rates for Medicare patients at nearly 6,000 hospitals nationwide that treated Medicare beneficiaries in 1986.

The seven volumes contained figures reflecting the mortality rate at each hospital for Medicare patients overall, as well as the rates for patients in each of 16 diagnostic categories, including cancer, kidney disease and stroke.

Each hospital's actual mortality rates were also compared with HCFA's calculation of what could have been expected for the hospital, given the mix of patients it treated.

Hospitals were given an opportunity to present written comments on the statistics, and these comments were published along with the numbers. We took great pains to explain the strengths and limitations of this information. We especially focused on the fact that this is a screening tool.

We decided to release this information not because it was required, but because it is an important contribution of the existing body of knowledge about health care.

The idea is to stimulate further work on methods for quality measurement. Quality measurement will remain a high priority on HCFA's agenda on into the future.

The advice we received from all parties was very helpful in helping us to shape a mortality information release that did just that: informed, rather than inflamed.

Now, we are working to move from focusing solely on hospital quality, to including that of other providers. Our release of hospital mortality information is one



BRIEF SUMMARY

CONTRAINDICATIONS

There are no known contraindications to the use of sucralfate

PRECAUTIONS

Duodenal ulcer is a chronic, recurrent disease. While short-term treatment with sucralfate can result in complete healing of the ulcer, a successful course of treatment with sucralfate should not be expected to alter the post-healing frequency or severity of duodenal ulceration.

Drug Interactions: Animal studies have shown that simultaneous administration of CARAFATE (sucralfate) with tetracycline, phenytoin, digoxin, or cimetidine will result in a statistically significant reduction in the bioavailability of these agents. The bioavailability of these agents may be restored simply by separating the administration of these agents from that of CARAFATE by two hours. This interaction appears to be nonsystemic in origin, presumably resulting from these agents being bound by CARAFATE in the gastrointestinal tract. The clinical significance of these animal studies is yet to be defined. However, because of the potential of CARAFATE to alter the absorption of some drugs from the gastrointestinal tract, the separate administration of CARAFATE from that of other agents should be considered when alterations in bioavailability are felt to be critical for concomitantly administered drugs.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Chronic oral toxicity studies of 24 months' duration were conducted in mice and rats at doses up to 1 gm/kg (12 times the human dose). There was no evidence of drug-related tumorigenicity. A reproduction study in rats at doses up to 38 times the human dose did not reveal any indication of fertility impairment. Mutagenicity studies were not conducted.

Pregnancy: Teratogenic effects. Pregnancy Category B. Teratogenicity studies have been performed in mice, rats, and rabbits at doses up to 50 times the human dose and have revealed no evidence of harm to the fetus due to sucralfate. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when sucralfate is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Adverse reactions to sucralfate in clinical trials were minor and only rarely led to discontinuation of the drug. In studies involving over 2,500 patients treated with sucralfate, adverse effects were reported in 121 (4.7%).

Constipation was the most frequent complaint (2.2%). Other adverse effects, reported in no more than one of every 350 patients, were diarrhea, nausea, gastric discomfort, indigestion, dry mouth, rash, pruritus, back pain, dizziness, sleepiness, and vertigo.

OVERDOSAGE

There is no experience in humans with overdosage. Acute oral toxicity studies in animals, however, using doses up to 12 gm/kg body weight, could not find a lethal dose. Risks associated with overdosage should, therefore, be minimal.

DOSAGE AND ADMINISTRATION

The recommended adult oral dosage for duodenal ulcer is 1 gm four times a day on an empty stomach.

Antacids may be prescribed as needed for relief of pain but should not be taken within one half hour before or after sucralfate.

While healing with sucralfate may occur during the first week or two, treatment should be continued for 4 to 8 weeks unless healing has been demonstrated by x-ray or endoscopic examination.

HOW SUPPLIED

CARAFATE (sucralfate) 1-gm tablets are supplied in bottles of 100 (NDC 0088-1712-47) and in Unit Dose Identification Paks of 100 (NDC 0088-1712-49). Light pink scored oblong tablets are embossed with CARAFATE on one side and 1712 bracketed by C's on the other.

Issued 1/87

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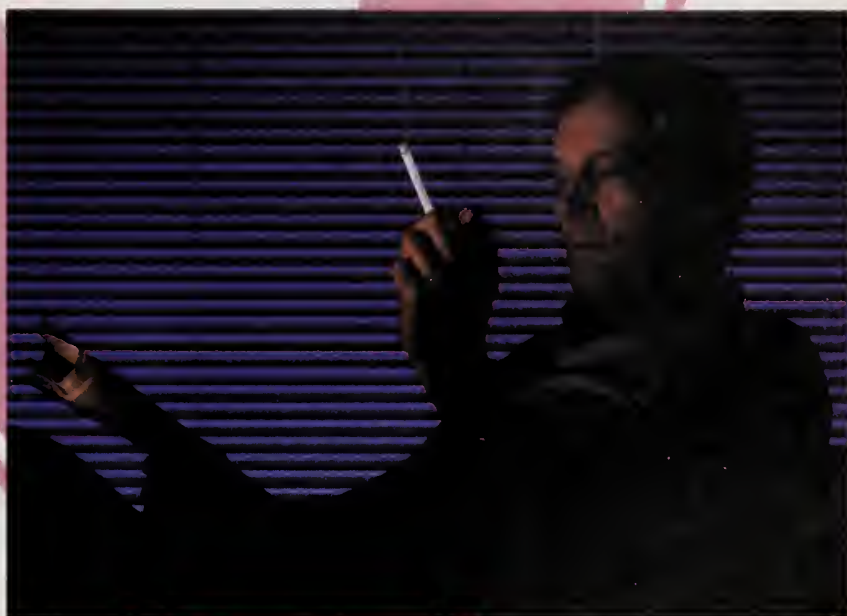
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continued on page 25

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Please see adjoining page for references and brief summary of prescribing information.

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ALLAN J. HAMILTON, M.D.

Neurosurgical Resident and Research Fellow,
Massachusetts General Hospital, Boston, Massachusetts.
Captain, U.S. Army Reserve.

EDUCATION Ithaca College, B.A. (Magna Cum Laude);
Hamilton College (Pre-med); Harvard Medical School.

RESIDENCY General Surgical Internship. Neurosurgical
Residency, Massachusetts General Hospital.

CONTINUING EDUCATION Neurology and Neuro-
surgery Research Fellowship Training, National Institutes
of Health.

OUTSTANDING ACHIEVEMENTS Olsen Memorial
Fellowship, National Masonic Medical Research Foundation;
Albert Schweitzer Fellowship, International Albert Schweitzer
Foundation; Harvard Medical School Cabot Prize for Best
Senior Thesis; recently published article, "Who Shall Live
and Who Shall Die" in Newsweek Magazine.



Soldier being examined for effects of high-altitude cerebral edema.

“The work I’m doing in the Army Reserve fits perfectly with my academic research interests in civilian life. The Army is very concerned with the effects of high-altitude cerebral edema, which is a mirror model of cerebral hypoxia, something I deal with every day in our neurosurgical intensive care unit. I couldn’t ask for a smoother transition. And that’s true for a lot of Reserve physicians. All we really do is change our clothes, not our mindset.

“Some of the projects the Army is undertaking are on the cutting edge of research. For example, I’m currently involved in developing for the Army a prototype of a non-invasive intracranial pressure-monitoring device that we hope will allow us to measure pressure changes as the brain swells—without drilling holes in the skull. If we can get our design to work, such a device could revolutionize high-altitude medicine as well as civilian neurosurgical care.

“The quality of medicine and the caliber of people I’ve been associated with in the Army Reserve are, without question, equal to civilian hospitals. In fact, I’m giving serious consideration to applying for an active duty academic position in Army Medicine when my residency ends at Massachusetts General.”

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step along a longer but essential road that I am convinced will lead us to be much better able to define and ensure quality in health care.

Effectiveness

We plan to spend much of 1988 focusing new attention on the next level of concern about quality: effectiveness. As overseer of the Medicare and Medicaid programs, HCFA has a responsibility to pay only for effective care.

We will best meet this responsibility by helping providers to know what care is effective and by helping beneficiaries to choose effective care.

Careful regulation in this area is, of course, important, but purely regulatory responses would inevitably become intolerably complex and lead to failure.

We must therefore use every part of the HCFA program to: inform beneficiaries; shape PRO review and feedback to providers; refine coverage and payment decisions; *AND* conduct demonstrations that highlight effectiveness and carry out research that measures effectiveness.

In the next year we will move to emphasize this responsibility for effective quality care and to assure that HCFA meets it with increased vigor and coordination.

We are convinced that this is a most important topic — though we are not yet certain about all the specific steps we will take.

A growing body of medical literature says that not all of the increased utilization of health care services are improving the quality of care. Studies by Wennberg, Brook and others are producing information that seriously questions how doctors are utilizing many medical procedures, including common angiography, carotid endarterectomy, upper GI endoscopy, cardiac pacemaker implants and coronary artery bypass grafting, to name a few.

We are developing an agenda that will closely focus on the central question of effectiveness in the practice of medicine.

This agenda involves many aspects of health research and payment policies. We will coordinate our work with other government agencies, including the Public Health Service. We would also like to involve the AHA, the AMA, and other provider groups, together with insurers, consumers and beneficiaries.

This emphasis on effectiveness of care is a central part of HCFA's future. It serves the interests of beneficiaries, providers, and taxpayers. Indeed, the agenda we set now will shape HCFA long after I have left office.

So much then for HCFA's efforts at quality care enhancement. We firmly believe there is a great merit in our work, especially in our hospital mortality information report.

Yet I wonder if the same can be said about the massive outpouring of health care legislation coming from Congress in recent years.

In his valedictory State of the Union Address, President Reagan dramatically demonstrated, both visually and manually, the current state of the art of federal legislation.

At one point, the President displayed Congress's recent handiwork, the massive concurrent resolution and budget reconciliation act. Combined, these two bills summed up an entire year's worth of negotiations over fiscal and budgetary policy.

One of those two massive bills, the Omnibus budget Reconciliation Act (or OBRA '87), contains literally thousands of lines of fine print affecting the Medicare program.

The draft implementation plan for OBRA '87 prepared by the staff of HCFA is 45 pages of fine print detailing the responsibilities facing the agency either in implementing the law, or drafting the regulations needed to implement it.

Another HCFA document, on the status of reports due to Congress contains another 24 pages of fine print, detailing the countless documents that Congress requires we prepare to assist their analysis of the Medicare program. How anyone can read them, let alone digest them and use them to formulate a coherent public policy, is another question entirely.

In the light of Congress's handiwork, I think it worthwhile to reflect on a sounder document, the 62nd *Federalist Paper*. In it, James Madison wrote:

"It will be of little avail to the people that the laws are made by men of their own choice if the laws are so voluminous that they cannot be read, or so incoherent that they cannot be understood; if they be repealed or revised before they are promulgated, or undergo such incessant changes that no man, who knows what the law is today, can guess what it will be tomorrow."

Perhaps Mr. Madison had premonitions of Medicare when he wrote that. He, like his fellow Founding Fathers, was well schooled in classical Greek and Latin. But I doubt even he could have deciphered the arcane declensions of Congressional newspeak that goes from OBRA to COBRA to SOBRA and back to OBRA again.

A major choice we continue to face in health care is whether to centralize or decentralize decision-making authority in the system.

Centralization does have some merits, but is limited in its ability to accommodate to local differences. It

is effective, however, in establishing the goals and standards that will make a decentralized "federal" system for health care benefits not only plausible but desirable.

Let me turn from this theoretical question about centralization and decentralization, and focus on the present and future of Medicare.

Prospective Payment

The Reagan Administration has made a major push for more competition (including market forces and appropriate incentives) in health care.

And much change has occurred in health care in the past few years — it is often described as a "revolution." Of course, a major part of this revolution took place in 1983, with the passage of the hospital prospective payment system.

It has had, far and away, the greatest effect on the health care system. It has given hospitals important incentives to deliver health services efficiently — and it is a dramatic improvement over the old cost-reimbursement system for hospitals.

But PPS is a centrally administered national price payment system, not price competition. The only "competition" among hospitals in PPS is non-price — in a continuing effort to maintain or increase patient volume.

One of the issues we have focused on more recently in HCFA is the continuing increase in cost per case under PPS. Despite strong incentives for holding costs down, they continue to rise.

On the one hand, this finding may lead us to conclude that we have not applied sufficiently firm pressure (not "squeezed hard enough") in order to give hospitals needed incentives to control costs.

Alternatively, we may have given hospitals a terribly difficult task. It is open to question whether hospitals really can control their costs further.

I believe a central point at issue is the degree to which hospitals truly can control physician decisions since, after all, it is predominantly the decisions of doctors that drive health spending.

We face a major question: to what extent Medicare really can safely economize further in the hospital sector.

Reducing the over-supply of hospital beds is one alternative. Given the low and still declining hospital occupancy rates in many parts of the country, one of the major ways we could hold down Medicare hospital spending is to find the political will to allow some hospitals to go out of business.

However, I believe it is implausible to put great reliance on such political will — especially given our current experience with the rural hospital sector.

As PPS has pinched more tightly in rural America, the Congress has responded with special rural rules and higher rural payment updates. Some of the changes

were well-warranted (and even advocated by HCFA as sound policy).

However, other changes — contemplated or proposed — fly in the face of knowledgeable observers who recognize that some rural hospitals need to change or even close.

Unfortunately, as time goes on, we are seeing the process becoming even more politicized to the point where local issues are given greater emphasis than overall national policy.

This is particularly problematic under PPS, since we only have national tools with which to deal with varying local markets. Adornment of a national program with local "fixes" underscores fundamental problems with such a nationally administered price system.

Consequently, we are beginning to have real doubts about further progress in restraining hospital spending under Medicare using PPS alone. To be clear, it is *far* superior to cost-reimbursement, but it has its own faults, not the least of which is its relative inability to deal with excessive utilization by physicians.

TPA

Another problem which threatens questions about the basic framework of PPS is the process of introducing new technologies. A highly visible case, which we are now facing, is how the Medicare payment process should respond to TPA and streptokinase, two new drugs used to treat heart attack patients, and proven to be of benefit, but priced very differently.

The issue is not coverage. Both drugs have been approved by the FDA for their safety and efficacy. The issue is payment — should there be some adjustment to account for the drug costs over the short term until update factors and DRG recalibrations take place 18 months from now.

I cannot tell you what our decision will be, but I can tell you this: we will consult carefully with all parties. Indeed, my staff and I have already met with leaders in the hospital industry and others.

We will also hear from clinical experts, researchers, and those in practice, and will speak also with providers, and with ProPAC, which has deliberated carefully over this same issue and recommended an overall increase in the PPS rates to account for TPA's costs.

PPOs

Part A expenditure growth is not Medicare's only problem by a long shot. Part B spending is literally out of control. This January, the Part B premium rose 38.5%.

This change is brought about by many factors, but chief among them is rapidly growing Part B outlays.

At a September 30 Ways & Means Committee hearing on this subject, I discussed the problem at length, emphasizing that it is not just a unit price phenomenon.

but is especially driven by burgeoning utilization of Part B services.

We know that much of the increase in utilization is good and to be applauded — it is doctors doing good for their patients. But we also know that some of this increase is unnecessary.

I believe we, especially now, need to question what has been a fundamental premise of the American health care system: "More is better." More is not necessarily better.

We need seriously to examine practice patterns and to reach consensus about appropriate patterns. Until recently the burden of proof in this debate has been on those who sought to have doctors (and others) provide less, in order to ensure that quality did not suffer.

As we look for ways to constrain Part B spending growth, using incentive payment systems like PPS for doctors will be difficult. Also, since utilization growth is the major component of outlay growth, price-only mechanisms like RVS fee schedules are not sufficient.

The best cost-control mechanism for physician services is a competitive system that puts patients through their own choosing under the care of physicians who are appropriate utilizers of services.

In exchange for increased patient volume, the physician agrees to pay a "price," that is, to submit to some tighter restraint.

The current Medicare participating physician program is the first step toward such a mechanism. Under this program, physicians receive enhanced volume and forego balance billing in their fees.

In economic terms, that is how we must take advantage of excess capacity — not with an administered price system, but by creating useful competition among providers.

By any reasonable measure we now have a glut of providers, both of doctors and of hospitals. It is a buyers' market and the federal government should take advantage of it.

Our near-term strategy for constraining Part B outlays likely will include price restraint, with limitation of the prevailing charge increase for non-primary care practitioners.

In addition, we will look to more intensive case-by-case utilization review to determine the necessity and the appropriateness of services.

We are also developing a possible Medicare physician payment reform proposal that embodies a broader set of principles involving both cost and quality: a preferred provider organization within the Medicare program.

We would select a sub-set of doctors — the careful and appropriate practitioners of quality medicine — and then steer a volume of patients to them using

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economic incentives, such as lower beneficiary copayments.

The doctors in the PPO would undergo more intensive utilization review, to ensure continued adherence to established norms. This is the basic concept of a Medicare PPO, but we are working on the important details.

PHPO

But, having told you about the problems we have in Medicare Part A and Part B, let me say clearly: There *is* a *better* way of dealing with these problems — the Private Health Plan Option under Medicare.

Under our uniquely American system of separation of powers with checks and balances, I believe it is much better to rely on a decentralized system and private health plans in Medicare.

Under a 1982 law change, much has been accomplished with HMOs and CMPs in Medicare. We have provided senior citizens with a choice. We now have Medicare risk contracts available as a choice for more than one-half of our 31 million beneficiaries.

And about one million have so chosen — to enroll in one of 158 plans in 34 states. The advantages of such plans to our beneficiaries are many — more benefits, lower copayments, less paperwork.

It is important for me to point out, though, that HMOs will need to prove themselves, not in competition with a fat and sassy traditional Medicare program, but one that is lean, mean and efficient. Also, Medicare is improving — witness the upcoming catastrophic coverage.

We are engaged in a “market test” of the Private Health Plan Option in Medicare. It is up to us in HHS to prove whether we can operate the program in a fair and beneficial manner — fair to the plans with whom we do business, so that these plans grow; and beneficial to the consumers served, so that they sell the concept to others.

We also seek to launch a series of demonstrations of another type of capitated plan — based on preformed groups of Medicare beneficiaries. The retired enrollees in an employer or union operated health plan would participate in a Medicare Insured Group demonstration. We recently signed an agreement with the Amalgamated Life Insurance Company to develop such a demonstration.

There are some (particularly in the Congress) who are skeptical about our demonstration ideas or about certain physician incentive payment arrangements. But remember that we face a problem — continuously growing Medicare outlays.

For my part — long term solutions need to depart from micromanagement and focus on decentralization, competitive forces, and incentives for the appropriate use of medical services. I believe this offers the best

hope for the future, controlling costs and improving quality.

Let me close with some additional reflections on the future.

We have a real contrast between the conventional wisdom and reality in health care. For example, the conventional view is that there have been major “cuts” in the Medicare program in recent years. In fact, Medicare has grown more rapidly than has defense in the period 1981 through 1987.

Further, there is the view that the American people value health so highly that they will pay any price, bear any burden, to have the finest in health care. The reality is much more complex than such sloganeering.

I believe we will always devote a large share of our economy to health care. However, what I think is growing is a demand for value in health spending. Value in the sense of paying for procedures and activities that are effective, and value in the sense of investing incremental dollars in ways that have the most return.

Surely there are limits to our resources. One of the uncomfortable realities, now dawning in the late 1980s, is that our aspirations have outstripped our resources. Therefore we must do a much better job of targeting our health care spending.

This will necessitate hard choices — by people of good will. As I have said at length earlier, I believe decentralized decisions of this sort are likely to prove better than centralized ones.

As we look carefully at the American health care system, I believe that — despite our deep-seated ambivalence about intruding on physician independence — we cannot have unfettered physician decision-making and slow health cost growth.

There is surely room for debate about *how* to constrain MD decision-making, but not *whether* to do so. As we analyze the system, is the glass half-empty, or half-full? In a time of change, the medical profession should not lose sight of its mission. Medicine must maintain its fiduciary role in caring for patients.

This means doing what you believe is best for your patients, but at the same time being committed actually to measuring your own performance and that of your colleagues — and acting on this information. In the long run this will be the main way the medical profession will maintain its credibility in this new age of information and accountability.

We must resist telling ourselves that the old ways were the best ways, and commit ourselves to the enterprise ahead.

I believe the policy I have described is one of vision, but a vision tempered by pragmatism. I believe that a more competitive, decentralized system of private providers and aware consumers will ensure a bright future for health care in America, at a price we all can afford.



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 T ROBIN HARDEN BRETT NEIL BORDENO
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INDERAL LA is their preferred beta blocker

...of the nearly three out of four physicians responding to the questionnaire, an impressive 97% rated **INDERAL LA** good to excellent for overall performance. Virtually all cited efficacy, tolerability, long-term cardiovascular protection and once-daily convenience as important factors in their choosing to prescribe **INDERAL LA**.

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...Virtually every responding physician rated patient satisfaction with **INDERAL LA** to be as good as, or better than, other beta blockers.

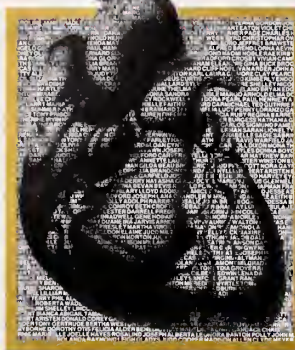
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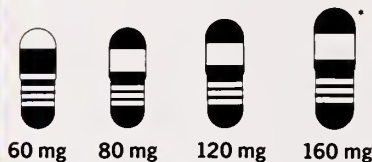
Please see next page for brief summary of prescribing information.

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(PROPRANOLOL HCl)
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60, 80, 120, 160 mg

The one you know best
keeps looking better



BRIEF SUMMARY (FOR FULL PRESCRIBING INFORMATION, SEE PACKAGE CIRCULAR.)

INDERAL[®] LA brand of propranolol hydrochloride (Long Acting Capsules)

DESCRIPTION. Inderal LA is formulated to provide a sustained release of propranolol hydrochloride. Inderal LA is available as 60 mg, 80 mg, 120 mg, and 160 mg capsules.

CLINICAL PHARMACOLOGY. Inderal is a nonselective, beta-adrenergic receptor-blocking agent possessing no other autonomic nervous system activity. It specifically competes with beta-adrenergic receptor-stimulating agents for available receptor sites. When access to beta-receptor sites is blocked by Inderal, the chronotropic, inotropic, and vasodilator responses to beta-adrenergic stimulation are decreased proportionately.

INDERAL LA Capsules (60, 80, 120, and 160 mg) release propranolol HCl at a controlled and predictable rate. Peak blood levels following dosing with Inderal LA occur at about 6 hours and the apparent plasma half-life is about 10 hours. When measured at steady state over a 24-hour period the areas under the propranolol plasma concentration-time curve (AUCs) for the capsules are approximately 60% to 65% of the AUCs for a comparable divided daily dose of Inderal Tablets. The lower AUCs for the capsules are due to greater hepatic metabolism of propranolol, resulting from the slower rate of absorption of propranolol. Over a twenty-four (24) hour period, blood levels are fairly constant for about twelve (12) hours then decline exponentially.

INDERAL LA should not be considered a simple mg-for-mg substitute for conventional propranolol and the blood levels achieved do not match (are lower than) those of two to four times daily dosing with the same dose. When changing to Inderal LA from conventional propranolol, a possible need for retitration upwards should be considered especially to maintain effectiveness at the end of the dosing interval. In most clinical settings, however, such as hypertension or angina where there is little correlation between plasma levels and clinical effect, Inderal LA has been therapeutically equivalent to the same mg dose of conventional Inderal as assessed by 24-hour effects on blood pressure and on 24-hour exercise responses of heart rate, systolic pressure, and rate pressure product. Inderal LA can provide effective beta blockade for a 24-hour period.

INDICATIONS AND USAGE. Hypertension: Inderal LA is indicated in the management of hypertension; it may be used alone or used in combination with other antihypertensive agents, particularly a thiazide diuretic. Inderal LA is not indicated in the management of hypertensive emergencies.

Angina Pectoris Due to Coronary Atherosclerosis: Inderal LA is indicated for the long-term management of patients with angina pectoris.

Migraine: Inderal LA is indicated for the prophylaxis of common migraine headache. The efficacy of propranolol in the treatment of a migraine attack that has started has not been established and propranolol is not indicated for such use.

Hypertrophic Subaortic Stenosis: Inderal LA is useful in the management of hypertrophic subaortic stenosis, especially for treatment of exertional or other stress-induced angina, palpitations, and syncope. Inderal LA also improves exercise performance. The effectiveness of propranolol hydrochloride in this disease appears to be due to a reduction of the elevated outflow pressure gradient which is exacerbated by beta-receptor stimulation. Clinical improvement may be temporary.

CONTRAINDICATIONS. Inderal is contraindicated in 1) cardiogenic shock; 2) sinus bradycardia and greater than first-degree block; 3) bronchial asthma; 4) congestive heart failure (see WARNINGS) unless the failure is secondary to a tachyarrhythmia treatable with Inderal.

WARNINGS. CARDIAC FAILURE: Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive heart failure, and its inhibition by beta blockade may precipitate more severe failure. Although beta blockers should be avoided in overt congestive heart failure, if necessary, they can be used with close follow-up in patients with a history of failure who are well compensated and are receiving digitalis and diuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitalis on heart muscle.

IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta blockers can, in some cases, lead to cardiac failure. Therefore, at the first sign or symptom of heart failure, the patient should be digitalized and/or treated with diuretics, and the response observed closely, or Inderal should be discontinued (gradually, if possible).

IN PATIENTS WITH ANGINA PECTORIS, there have been reports of exacerbation of angina and, in some cases, myocardial infarction, following abrupt discontinuance of Inderal therapy. Therefore, when discontinuance of Inderal is planned, the dosage should be gradually reduced over at least a few weeks, and the patient should be cautioned against interruption or cessation of therapy without the physician's advice. If Inderal therapy is interrupted and exacerbation of angina occurs, it is usually advisable to reinstitute Inderal therapy and take other measures appropriate for the management of unstable angina pectoris. Since coronary artery disease may be unrecognized, it may be prudent to follow the above advice in patients considered at risk of having occult atherosclerotic heart disease who are given propranolol for other indications.

Nonallergic Bronchospasm (eg, chronic bronchitis, emphysema) — PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD IN GENERAL NOT RECEIVE BETA BLOCKERS. Inderal should be administered with caution since it may block bronchodilation produced by endogenous and exogenous catecholamine stimulation of beta receptors.

MAJOR SURGERY: The necessity or desirability of withdrawal of beta-blocking therapy prior to major surgery is controversial. It should be noted, however, that the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.

INDERAL (propranolol HCl), like other beta blockers, is a competitive inhibitor of beta-receptor agonists and its effects can be reversed by administration of such agents, eg, dobutamine or isoproterenol. However, such patients may be subject to protracted severe hypotension. Difficulty in starting and maintaining the heartbeat has also been reported with beta blockers.

DIABETES AND HYPOGLYCEMIA: Beta blockers should be used with caution in diabetic patients if a beta-blocking agent is required. Beta blockers may mask tachycardia occurring with hypoglycemia, but other manifestations such as dizziness and sweating may not be significantly affected. Following insulin-induced hypoglycemia, propranolol may cause a delay in the recovery of blood glucose to normal levels.

THYROTOXICOSIS: Beta blockade may mask certain clinical signs of hyperthyroidism. Therefore, abrupt withdrawal of propranolol may be followed by an exacerbation of symptoms of hyperthyroidism, including thyroid storm. Propranolol may change thyroid function tests, increasing T_4 and reverse T_3 , and decreasing T_2 .

IN PATIENTS WITH WOLFF-PARKINSON-WHITE SYNDROME, several cases have been reported in which, after propranolol, the tachycardia was replaced by a severe bradycardia requiring a demand pacemaker. In one case this resulted after an initial dose of 5 mg propranolol.

PRECAUTIONS. GENERAL: Propranolol should be used with caution in patients with impaired hepatic or renal function. Inderal (propranolol HCl) is not indicated for the treatment of hypertensive emergencies.

Beta-adrenoceptor blockade can cause reduction of intraocular pressure. Patients should be told that Inderal may interfere with the glaucoma screening test. Withdrawal may lead to a return of increased intraocular pressure.

CLINICAL LABORATORY TESTS: Elevated blood urea levels in patients with severe heart disease, elevated serum transaminase, alkaline phosphatase, lactate dehydrogenase.

DRUG INTERACTIONS: Patients receiving catecholamine-depleting drugs such as reserpine should be closely observed if Inderal (propranolol HCl) is administered. The added catecholamine-blocking action may produce an excessive reduction of resting sympathetic nervous activity which may result in hypotension, marked bradycardia, vertigo, syncope attacks, or orthostatic hypotension.

Caution should be exercised when patients receiving a beta blocker are administered a calcium-channel-blocking drug, especially intravenous verapamil, for both agents may depress myocardial contractility or atrioventricular conduction. On rare occasions, the concomitant intravenous use of a beta blocker and verapamil has resulted in serious adverse reactions, especially in patients with severe cardiomyopathy, congestive heart failure, or recent myocardial infarction.

Aluminum hydroxide gel greatly reduces intestinal absorption of propranolol.

Ethanol slows the rate of absorption of propranolol.

Phenyltin, phenobarbital, and rifampin accelerate propranolol clearance.

Chlorpromazine, when used concomitantly with propranolol, results in increased plasma levels of both drugs.

Antipyrine and lidocaine have reduced clearance when used concomitantly with propranolol.

Thyroxine may result in a lower than expected T_3 concentration when used concomitantly with propranolol.

Cimetidine decreases the hepatic metabolism of propranolol, delaying elimination and increasing blood levels.

Theophylline clearance is reduced when used concomitantly with propranolol.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY: Long-term studies in animals have been conducted to evaluate toxic effects and carcinogenic potential. In 18-month studies in both rats and mice, employing doses up to 150 mg/kg/day, there was no evidence of significant drug-induced toxicity. There were no drug-related tumorigenic effects at any of the dosage levels. Reproductive studies in animals did not show any impairment of fertility that was attributable to the drug.

PREGNANCY: Pregnancy Category C. Inderal has been shown to be embryotoxic in animal studies at doses about 10 times greater than the maximum recommended human dose.

There are no adequate and well-controlled studies in pregnant women. Inderal should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

NURSING MOTHERS: Inderal is excreted in human milk. Caution should be exercised when Inderal is administered to a nursing woman.

PEDIATRIC USE: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS. Most adverse effects have been mild and transient and have rarely required the withdrawal of therapy.

Cardiovascular: Bradycardia; congestive heart failure; intensification of AV block; hypotension; paresthesia of hands; thrombocytopenic purpura; arterial insufficiency, usually of the Raynaud type.

Central Nervous System: Light-headedness; mental depression manifested by insomnia, lassitude, weakness, fatigue; reversible mental depression progressing to cataplexy; visual disturbances; hallucinations; vivid dreams; an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics. For immediate formulations, fatigue, lethargy, and vivid dreams appear dose related.

Gastrointestinal: Nausea, vomiting, epigastric distress, abdominal cramping, diarrhea, constipation, mesenteric arterial thrombosis, ischemic colitis.

Allergic: Pharyngitis and agranulocytosis, erythematous rash, fever combined with aching and sore throat, laryngospasm and respiratory distress.

Respiratory: Bronchospasm.

Hematologic: Agranulocytosis, nonthrombocytopenic purpura, thrombocytopenic purpura.

Auto-immune: In extremely rare instances, systemic lupus erythematosus has been reported.

Miscellaneous: Alopecia, LE-like reactions, psoriasisiform rashes, dry eyes, male impotence, and Peyronie's disease have been reported rarely. Oculomucocutaneous reactions involving the skin, serous membranes and conjunctivae reported for a beta blocker (practolol) have not been associated with propranolol.

DOSAGE AND ADMINISTRATION. Inderal LA provides propranolol hydrochloride in a sustained-release capsule for administration once daily. If patients are switched from Inderal Tablets to Inderal LA Capsules, care should be taken to assure that the desired therapeutic effect is maintained. Inderal LA should not be considered a simple mg-for-mg substitute for Inderal. Inderal LA has different kinetics and produces lower blood levels. Retitration may be necessary, especially to maintain effectiveness at the end of the 24-hour dosing interval.

HYPERTENSION — Dosage must be individualized. The usual initial dosage is 80 mg Inderal LA once daily, whether used alone or added to a diuretic. The dosage may be increased to 120 mg once daily or higher until adequate blood pressure control is achieved. The usual maintenance dosage is 120 to 160 mg once daily. In some instances a dosage of 640 mg may be required. The time needed for full hypertensive response to a given dosage is variable and may range from a few days to several weeks.

ANGINA PECTORIS — Dosage must be individualized. Starting with 80 mg Inderal LA once daily, dosage should be gradually increased at three- to seven-day intervals until optimal response is obtained. Although individual patients may respond at any dosage level, the average optimal dosage appears to be 160 mg once daily. In angina pectoris, the value and safety of dosage exceeding 320 mg per day have not been established.

If treatment is to be discontinued, reduce dosage gradually over a period of a few weeks (see WARNINGS).

MIGRAINE — Dosage must be individualized. The initial oral dose is 80 mg Inderal LA once daily. The usual effective dose range is 160-240 mg once daily. The dosage may be increased gradually to achieve optimal migraine prophylaxis. If a satisfactory response is not obtained within four to six weeks after reaching the maximal dose, Inderal LA therapy should be discontinued. It may be advisable to withdraw the drug gradually over a period of several weeks.

HYPERTROPHIC SUBAORTIC STENOSIS — 80-160 mg Inderal LA once daily.

PEDIATRIC DOSAGE — At this time the data on the use of the drug in this age group are too limited to permit adequate directions for use.

*The appearance of these capsules is a registered trademark of Ayerst Laboratories.

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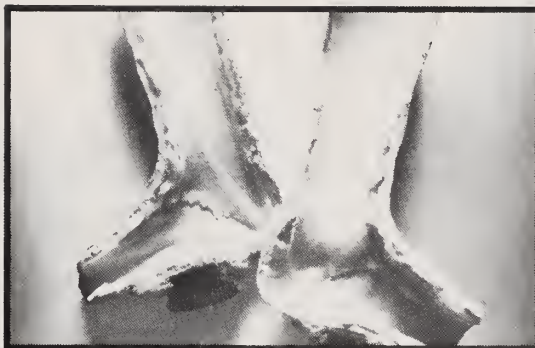
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Form No. 3344

Medicine and God: Is God Obsolete?

Charles H. Smith, M.D.*

Abstract

The common goals of religion and medicine over many centuries is recognized along with an apprehension that such a Golden Era of mutual effort may be ending.

While admitting that the few subjects discussed are not necessarily those of primary importance, it seems obvious that the author is addressing the few which he considers of primary importance during current times and conditions. While it is very clear that the writer is Christian, it is hoped that he has not belittled or in any way insulted other faiths.

The importance of physical contact between patient and physician is emphasized while cautions are noted. The seeming failure of the Academic Physician's willingness to approach this subject is lamented as is the resulting ignorance of the young student/physician. The writer concludes that this failure is detrimental to physician and patient. Perils confronting the female physician in this area are discussed.

The contributions of Jewish physicians are both recognized and criticized.

The problem of Christians and other faiths' relationship to Islam is examined but no firm

resolution is reached. Some probably undesirable and almost surely unattainable resolutions are viewed.

The present views and absurdities of our culture's approach to homosexuality are observed at some length.

The briefest of summaries is presented.

Finally, it is hoped that the indispensable role of God in all of our endeavours is reverently accorded its just due.

Introduction

For quite a good many centuries Medicine and Divinity worked in close collaboration. There have been exceptions and many. It is difficult to conceive that the God we believe we now know could look with favor upon the Inquisition or later the burning of witches. Temporary divergences of thought and action are common.

What we might begin to wonder today is whether medicine and religion are on unavoidable collision courses. Some thoughts seem worth exploring and will be. The ultimate decision may be "Does greed transcend God?"

Subjects presented for contemplation and discussion are not presented in any imagined order of importance, simply as they come to mind. And they are presented

*Psychiatry, 1900 Walnut St., Montgomery, AL 36106.

with no malice toward any religion or any Deity. Certain "inalienable rights" must surely include the right to choose our own God and favor the teachings of that God, regardless of our country of origin.

The Laying On of Hands

The laying on of hands is favorably viewed by the Bible. Genesis 49:14, Acts 6:6 and 19:6 are among many references. It is true that these pertain primarily to those to be designated as Holy and few physicians would place themselves among the Holy. But the doctor remains something special, if not holy, among most patients. He is largely responsible for the well being and temporal life span of his patient. The physician will retain this position since no other professional is trained in such a fashion as to replace him. Other professionals may demean him, sue him, even ruin his life and that of his family. But no, they cannot deprive him of his training.

The brief pat on the shoulder can quite often have more therapeutic value than a lengthy dissertation on the pathology of diabetes, hypertension or schizophrenia. If we are fearful that a pat on the shoulder might be misinterpreted as a sexual advance we just ought to get out of medicine. *Fear and good medicine are not compatible.* That is it. Thus it has been and thus it will remain. The doctor who fears to touch his patient is not a doctor at all. He is someone who wasted a number of years in an elusive pursuit of medical study.

It is distressing that the resident physician and young practicing physician seem unaware of the value of some physical contact. Can a minister or priest baptize without touching the person to be blessed? No, he cannot. The physician is not (or rarely) minister, priest or rabbi but at some point he is going to be a person who is going to be *the* person responsible for the physical or mental happiness of the patient and ultimately the life of that patient. There is no room for the fearful or legally overly cautious doctor. Situations arise when it is necessary to observe the Trumanesque admonition to the effect that if one is unable to stand the heat one should leave the kitchen.

When we speak of hands, we may be inclined to wonder what happened to the shaking of hands. A handshake takes only a few seconds. It can mean a lot — "I'm glad to meet you, I look forward to working with you, I hope we can work together to your benefit." The handshake remains an essential, mostly meaningless, gesture in social situations but has largely disappeared from the emergency room where it is often sorely needed. It has become of primary importance to shake out one's insurance card, fill out papers, then wait and wait. With some luck the patient and family are eventually herded to an examination room where they wait and wait. Eventually a physician may appear. Probably he will not show the simple courtesy and

grace of a handshake or brief apology for any unnecessary delay. More likely he will appear overworked, fatigued and harried. So what is new? When have physicians not been harrassed, harried and hurried? Never in the writer's experience has it been otherwise. But only recently in that experience has the doctor forsaken common civility, handshake very much included.

Likely there is no literature on the subject but one feels that God would approve the handshake and that the Dieties of other than Christian religion would share that approval. We would think that even today's Allah's Islam, or perhaps Islam's prefabricated Allah, would prefer to shake the hand prior to its amputation. A little more later.

It does seem that the female physician dealing with the male patient may labor at some disadvantage. The shoulder pat might be at increased risk of misinterpretation or, in the case of an attractive physician, wishful thinking converted through rationalization to misinterpretation. The handshake may signal to the male patient an overly aggressive female. This same patient might be entering the office with physical or emotional symptoms directly traceable to an overly aggressive spouse. There are, however, verbal substitutes available until a firm doctor/patient understanding is established. One can always borrow a sentence or two from Carl Rogers. "You seem a very nice person." We all like to be thought of as nice persons and few patients could, in moments of most parataxic thinking, twist such a statement into any semblance of a sexual proposition. Those who have watched on videotape an initial interview by Dr. Rogers may leave with a puzzled shake of the head. With his bald head, glasses, squirrel like cheeks, cherubic smile, he captures the patient completely. What in the world does he do for an encore? Surely he has exhausted all of his considerable charm during session one. But he also possesses considerable intellect and this must be the answer to our question.

Of course, we may not consider our patient a nice person at all, we may view him as a slob. Common courtesy combined with a healthy mixture of cowardice permits some degree of hypocrisy. We would also do well to remember that the patient suffering a panic attack is little given to social amenities. He may only seem a slob. He may later seem quite a nice person.

The evolution and modernization of medicine has all but eliminated anything other than elective physical contact. It is easier and perhaps, but only perhaps, more informative to scan a liver or bounce sound waves off a gall bladder than to bother with palpation, percussion or even reasonably comprehensive history taking.

It is terribly easy and terribly expensive to cast the laboratory and X-ray departments in the general direction of the patient. One lab finding demands an-

other, one scan precipitates another. These expenses are destroying the opportunity for elderly and poor patients to receive adequate care, sometimes any care at all. Is this ungodly? Is God a miser? Well, Jesus was not born at the Bethlehem Hilton.

There is little more to be done than to repeat and summarize. Meaningful physical contact is both important to the patient's well being, it is consistent with those religious principles which most of us were taught as children. Unnecessary laboratory and X-ray work which we know will now, not eventually, deprive the old and poor of needed care require close attention by the physician, not by some amateur inspection team.

The history and physical examination cannot be replaced by the most advanced of machines. The Doctor who sometimes sees fit to pray quietly for Divine assistance may be the wisest of physicians.

The academic physician will determine in which order the student/resident sets goal directions. The teacher has every right to be Atheist, Christian, Hindu, Islamic or nothing at all. What the teacher does have an obligation to do is teach an humanitarian approach. If he/she does this, then the student, without obligation to any religion, is, in fact, following the tenets of Christian religion and most other religions as we know them.

The writer recently watched a television show during which a young physician serving a mandatory term in a rural area announced his intention to vacate that area after his term had expired. A family practice physician, he explained that he intended to depart the area because it failed to provide the facilities he was trained to use. Sounds reasonable. But the doctor possessed a head, presumably a brain, two eyes, two apparently well coordinated hands, in general, what seemed an intact body. The "facilities" which the doctor lacked must therefore be laboratory/pathology and X-ray. One does not criticize machines or laboratories, rather one offers thanks to those who have provided advanced technology and its availability, repeat *availability*. There are few areas so rural that special studies are not available within a score or two miles. Automobiles and ambulances are at hand.

What remains to be asked is whether during seven or more years of training, did the physician's instructors/professors/heads of department bother to teach the brain to take competent history or the hands and eyes to do a physical examination? Apparently they did not bother and, if not, why not? This is a question which will not be answered because a quest would have to begin at the top. The top is beyond reproach.

There could be a Divine Plan to replace human physicians with robot physicians and this probably could be accomplished within a decade. But it is very hard to imagine that God intended that humans should be treated by other than humans.

The Christian Physician

Nearly all physicians will occasionally be questioned regarding their religion, especially if they bear a foreign sounding name. The psychiatrist will fairly often be asked "Are you a Christian Psychiatrist?" even if his name be Brown, Jones or Smith. If the name happens to be Smith, there is a contraction of the muscles of mastication, narrowing of lids, some furrowing of the brow. Yet the patient has every right to ask the question. After some experimentation, the writer has not implemented a satisfactory answer. "No, just a Methodist" may not entirely satisfy the patient but it does terminate the subject. It does not really satisfy the physician. Is the patient saying that it is satisfactory for a "heathen" to administer an injection of penicillin but only the Christian is competent to pen a prescription for an antidepressant? Again, the patient has a right to his opinion. There are yet other considerations.

Had I been born in another country and raised a Hindu or Buddhist, would this, of religious necessity, mean I would have less interest in my patient's recovery? Absurd. I might have different approaches, I might have communication problems to master, I might address God by another name. But I would remain me. I cannot believe that I would be deprived by any God of the right to be me.

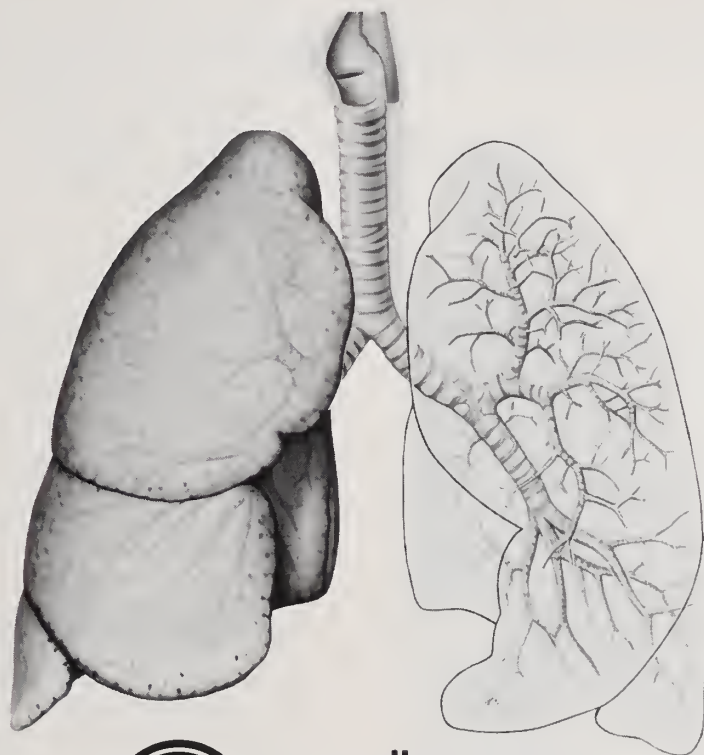
Hippocrates was not a Christian. He addressed Apollo and other gods. Yet the Oath would raise no brows and few questions should one encounter it in the Bible. It is a good and eternal oath. It is clear and it leave no room for misunderstanding or manipulation. It tells the physician in no uncertain terms what he may and may not do. And it is being increasingly violated. It is violated by every physician who works exclusively for a profit only hospital. Medicine was not conceived as a profit only proposition. More a way of life really. Any doctor is invited to rationalize his way around Hippocrates. It can't be done. It is almost as though Hippocrates anticipated the medicine-for-money-only organizers.

Most doctors do earn a better than average income. But they do *earn* it and they have paid for it, in money, in lost sleep, in periods of anxiety and of embarrassment and of humiliation and what sometimes seems unbearable fatigue. Most patients know this and don't begrudge it. They may wonder what sort of off center thinking motivates us and they may pose a question about motivation which we cannot answer. But they are not angry.

Above average income is one thing, extravagant wealth another. Those physicians who use their medical degrees as stepping stone to riches may or may not earn Divine approval. Eventually they will find out.

continued on page 38

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CECLOR SHOULD BE ADMINISTERED CAUTIOUSLY TO PENICILLIN SENSITIVE PATIENTS. PENICILLINS AND CEPHALOSPORINS SHOW PARTIAL CROSS-ALLERGENICITY. POSSIBLE REACTIONS INCLUDE ANAPHYLAXIS.

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Therapy-related adverse reactions are uncommon. Those reported include:

- Gastrointestinal (mostly diarrhea): 2.5%.
- Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment.
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- Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy.
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ousness, insomnia, confusion, hypertonia, dizziness, and somnolence have been reported.

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Medicine and God

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The exploiters of their degrees are not to be confused with the doctor who simply happens to be an excellent and exceptional businessman. These physicians would have been wealthy had their degrees been in Art Appreciation.

It seems sometimes convenient to forget that Jesus was a Jew. This is obvious when we see Klan members in standard uniform of robe and burning cross. The cross signifying Arayan superiority or whatever superiority is convenient at a given time. Christ's death was not ordered by Blacks or Jews but by a Roman, possibly a reluctant one, but all the same a Roman. This we are taught is historical fact.

It is difficult to think that prejudice could exist in modern medicine. It may linger to some degree but not to the socioeconomic deprivation of the Black or Jewish physician. The Black physician who has some recent historical justification for apprehension does not really seem concerned, nor need he be. It never remains for long a secret that some Jewish physicians adopt "Christian" names in order to avoid non-existent "prejudice"; such physicians are either misguided or plain paranoid. In the latter case, they should seek treatment before their families must.

Jewish doctors have contributed and continue to contribute mightily to the medical literature and in disproportionately high percentage. Their contributions are oriented both toward research and clinical medicine. Should the author seek to find fault in their writings, it would be toward their relentlessly serious approach, a lack of humor which is certainly not lacking in the individual. This might be interpreted as a fault of the author and with good cause. Medicine is, after all, often a matter of life and death. Yet one must wonder whether this seemingly unwritten law barring humor might inhibit many Jewish physicians from meaningful contributions. The historical road to the top has been long and hard, convoluted, even deadly for many Jewish doctors. It may require a few more comfortable generations before they see humor in their scientific selves.

Sigmund Freud would necessarily be the one physician of any ethnic group who already, a little less than fifty years after his death, has earned a very permanent place in the literature, any literature. He, by his own admission, was a very reluctant atheist. Atheist in the sense that, while he appreciated, perhaps even envied, those able to take comfort in their religious beliefs, his own scientific convictions did not allow him to share those beliefs (*Civilization and Its Discontents*, 1939).

Is Freud the Atheist then doomed? He was sometimes petulant, sometimes gloomy. He was given to telling ribald jokes at psychoanalytic conventions pur-

posely to make these conventions meaningful rather than a clash of larger-than-life egos. He was a man large enough to find humor in his own thoughts and actions and those of others (*Jokes and Their Relationship to the Unconscious*). Primarily though, he was Professor Freud, the relentless scientist. Fundamentally work, a little time for relaxation and family.

The question remains is Freud the Atheist doomed? This person who contributed so much, gave so much and suffered so much. No, if we believe in a forgiving God we must believe that Freud is in his rightful place.

For more years than perhaps anyone can recall we have spoken of Judeo-Christian principles and ethics. We seem to have agreed to not argue the question of whether the Son of God has arrived or has yet to arrive. There have been political disagreements between the United States and Israel and they are very obvious, not clear, but obvious, at many junctures and these are present at this time. Regardless of the outcome of two stubborn peoples' lack of political agreement, the fact of Judeo-Christian ethics will not be affected. They seem too similar to be challenged by the politics of today or another day.

In psychiatry, there are a certain number of physicians who proclaim and may even advertise themselves as "Christian Psychiatrists." Where in the world does that leave the rest of us? Are we by implication Atheists? Sinners? Persons not worthy of patient communion? Adherents of Satan? All of these and more? The list could go on and on. The surprise is not that these physicians lacking in ethics exist. The confounding thing is that patients of intelligence and educations allow themselves to be taken in by such phonies. Not all such physicians can be called phonies in the usual sense. Some and some by virtue of training in strongly religious oriented medical schools probably consider themselves the religious superiors of their peers. The writer while in basic training at Fort Sam Houston occupied a cubicle opposite a California educated holiness type medical graduate. The writer's efforts to gain some knowledge of the Napoleonic wars and the role of the Duke of Wellington were periodically punctuated by the prayers of the occupant opposite. They were holy and sincere prayers delivered on hands and knees. They positively gave no opportunity for satisfaction of the urge to physically attack, although both the Emperor and the Iron Duke seemed to urge me on.

Deprived of any opportunity to verbally or physically assault that Super Christian who both interfered with my reading and my sleep (daylight prayers), it seemed only reasonable to make his acquaintance. He was a very nice person who alternately either blessed me or pitied my ignorance. His knowledge of things Holy was profound. His knowledge of things medical

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was pathetic. If there is a moral here, it seems obvious. The God, the same God, of the Californian and the Alabamian would, one thinks, expect of the physician, some Biblical knowledge but sufficient medical knowledge to go forth and care for the ill and to do so with efficiency. The Californian was about to assume duties for which he simply was not competent.

Thus the writer felt only a little guilty about asking this physician whether he faced Mecca during his ritual prayers. It would not seem sacrilegious to assume that God would settle for faith in the young physician while insisting upon the best medical knowledge available to him.

Of that cynic, that person who advertises in announcement cards, or, for Heaven's sake, in a newspaper that he/she is a "Christian Psychiatrist" there is only one thing to be said: he is an abomination. He is deserving of neither recognition by Christ or acceptance by medicine. The truly Christian physician will be recognized by his concern, his actions, by the ethic that demands he learn more and more of medicine and apply that knowledge to his patients. He will not find advertisements necessary. His efforts and accomplishments are the only advertisements either necessary or morally acceptable.

Christianity and Islam

LA-ELA-HA-IL-LAL-LA-HO MO-HUM-MA-DUR Ra-soo-lol-lah.

"There is no God but Allah and Mohammed is his prophet." A native Meccan born in 570 A.D., the Prophet seemingly did not enjoy great job security either as prophet or religious leader although he fathered a religion which affected millions of Islamites as well as many non-believers.

The inexplicable happenings in the Middle East eventually compelled the author to review texts owned since some college courses in introduction to religion. Mohammed seemed comparable to a rookie quarterback, heroic until a couple of fumbles and interceptions. Following an error or two, a kingdom of coaches wanted him benched. He did survive and eventually became both prophet and "Master of Arabia," a multi-talented quarterback. Should Jackie Kemp, quarterback turned politician, by some scarcely conceivable happening, realize his Presidential ambitions, he would deserve to be termed Prophet and Washington his Mecca.

A scholarly definition goes "Into its (Islam's) formation were woven elements from the native Arabian faith, a great deal from Judaism and not a little from Christianity as those were understood, the whole colored by the unique personality of the Prophet." This definition does go a long way toward explaining why

we will never understand Islam. It does not really explain those acts of violence and seemingly senseless wars, although one can reasonably argue that all wars are senseless.

The "... unique personality of the Prophet," does that offer a clue? There are would-be prophets in Iran, Iraq, Syria and the migratory PLO. Are they willing to commit or condone repeated atrocities in an effort to establish the uniqueness of Mohammed? If so, their efforts are in vain but so at times seemed those of the Prophet. Are they Neanderthal quarterbacks playing on a bloody field? This is only a thought and not a comforting one. Present aspiring Prophets will not survive forever but there are many substitutes sitting on the bench. Barring military conquest or strict agreement among the Super Powers to isolate Offending Countries, this type of violence seems destined to go on forever. Our own country could initiate isolation by stopping all intercourse with certain countries but we are not likely to leave a vacuum too easily filled by the Soviets nor would we be willing to further isolate Israel. But the whole thing is only a thought and probably a tangential one.

A more comforting and more probable thought is that the God we share will weary of needless bloodshed. God has shown impatience in the past.

Religion and Homosexuality (and Hysteria)

AIDS has not been kind to those choosing a lifestyle differing from that of the majority. People rant of Divine retribution, a punishment for the homosexual and bisexual. They ignore the intravenous drug user, the African, the infant with AIDS, the growing number of heterosexuals with the disease.

The whole subject could simply be dismissed as an hysterical reaction were the Bible not quite so explicit in its disapproval. The beginning minister or priest is quite well aware that much of the Biblical writing is symbolic but at present he is hard put to read symbolism into Biblical injunctions regarding homosexuality. We know a substantial number of priests are homosexual, a substantial number of physicians, a substantial number of everybody. We all know and have friends who are homosexual or bisexual and we would not consider surrendering their friendship for that reason.

We can and must dispel myths. If God intended AIDS as punishment for homosexuals, bisexuals and prostitutes. He jolly well took his time about deciding to invent a lethal virus. We do not believe He approves of abortion on request, i.e., without medical indication, but He has not yet cast a pox upon the Supreme Court. The court is very well aware that they violated the Constitution by creating judicial legislation in *Brown versus School Board* but they did not imprison themselves.

The writer's own experience in acquaintance with

homosexuals suggests that they are kind, generous, fair-minded and more tolerant than are their "normal" counterparts.

Psychiatry, not with everyone's approval, has been among the leaders in empathy toward homosexuals. DSM-I listed homosexuals as a sort of psychopathic deviant, which was nonsense. The American Psychiatric Association removed homosexuality *per se* from DSM-II in 1973. By no means were all psychiatrists/psychologists happy. A diagnosis of "Ego Dystonic Homosexuality" was included in DSM-III, a partial surrender to a relatively small number of psychiatrists who continued to feel that homosexuality must somehow be pathological. In the summer of 1986, the APA removed that label in DSM-III-R, thus acknowledging that a person's sexual preference is not a disease entity. A good while before any of this, Rado and others recommended public tolerance provided no moral or legal laws were broken, e.g., there was no sexuality with minors.

This should, for psychiatry, at least, settle the matter. Not entirely. In Freud's study of *A Case of Demential Paranoides*, the Professor, in his customary logical one, two, three manner, painted a seemingly reasonable progression from homosexuality to paranoia. The author does not agree. Obviously the Paranoid Schizophrenia is a confused person. He may father one or more children and he may have one or more homosexual experiences. He may try cocaine (as did Freud), PCP, or any number of drugs. He may have homicidal or suicidal urges and occasionally he may satisfy, more properly, lay to rest, these urges. He is not a homosexual, an addict or a murderer although he may have dabbled at all three. The law usually allows only one dabble into murder and quite a few paranoids are in prison where they are sexually vulnerable to the psychopath. We do now have medications, antipsychotic medications, which are effective and which often offer the Schizophrenic an opportunity to adopt the lifestyle of his choosing. These were not available during Freud's lifetime. Given the opportunity to observe the Schizophrenic in remission rather than regression, Freud might well have reconsidered his thinking on the psychoses.

The above paragraph may seem an unnecessary diluent and perhaps is. But all psychiatrists have read of the paranoid Dr. Schreber and many other physicians will recall a lecture or reading linking paranoia and homosexuality. Dr. Schreber, protagonist of *Dementia Paranoides* was incidentally a doctor of law, not medicine.

We casually invite our children to wonder how many angels might share the head of a needle. We might more prudently consider what percentage of us may be classified sinners in relation to the entire population for any given reason. If we accept the frequently offered percentage of 10% homosexuals/lesbians, then a relatively large number of persons are off to Hell. Throw in those adolescents who practice such homosexual equivalents as mutual masturbation and the number grows. Add all violators of the Ten Commandments and Heaven looms as a rather lonely place, Satan as an overworked and frustrated host. Poor Satan may be driven to the brink when he is forced to deal with competitive hosts in the persons of television evangelists. In the event of a Satanic nervous breakdown, there should be plenty of psychiatrists around to lend a hand; ideally he should be treated by a "Christian Psychiatrist." They will all be around.

We tend to forget that the Bible was written not by God but by men, and clergymen may be among the worst offenders in terms of such memory lapses. A few clergymen seem to forget that they themselves did not write the Bible. We feel that the writers were mostly Divinely inspired. Mostly. Not necessarily all. Even if all, they were men and men are subject to error and to the interpersonal pressures of the prejudice of others. This is fact and it is fact that requires no elaboration.

We recall that Jesus had something to say about casting the first stone. It may be, it may very well be, that we are demeaning ourselves in our hounding of homosexuality. We might be better advised to go covet our neighbor's wife or something. Anyone who has not coveted his neighbor's wife probably has just had an unfortunate run of neighbors.

Summary and Conclusion

God is not subject to summary. Neither can the physician's relationship to God be summarized. We are granted the right to seek help or to go it alone.

It can be awfully reassuring to know that we are traveling with a companion. □

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Pharmacologic Management of Chronic Pain in the Cancer Patient

Steven H. Stokes, M.D.*

Introduction

All of us that care for patients with cancer are faced with managing chronic pain. Estimates are that 60-90% of patients with advanced disease will have substantial discomfort and for the terminally ill, 25% will die of uncontrolled pain.¹ Unrelenting, intractable pain is the symptom most feared by cancer patients and their families.²

Unfortunately, the management of chronic cancer pain is not adequately covered in medical schools or residency training programs. Most of us are trained to care for the acute pain of trauma or ischemic heart disease. In these situations, patients are anxious and agitated; however, with adequate doses of short-acting narcotics their symptoms can be controlled while recovering from the acute event. The chronic pain of cancer is different. With prolonged, uncontrolled pain, there is an evolution of affect leading to depression, withdrawal and ultimately hopelessness and despair. It is essential to break the cycle of pain early such that even the terminally ill may experience a good quality of life and minimize the burden of their care.

The initial evaluation of the patient with chronic cancer pain requires that the physician accept as fact the patient's description of their discomfort. The intensity of pain does not always correlate with the degree of abnormality seen on the x-ray or scans. It is important to determine what impact the pain has on the patient's quality of life regarding sleep patterns,

mood or daily activities. The goal of therapy is to return the patient, if at all possible, to an independent normal lifestyle.

Principles of Pain Management

The factors most frequently identified which account for inadequate pain relief include inadequate medication on the part of physicians and nurses or delay in instituting aggressive therapy.³ Patient non-compliance due to fear of addiction or confusion in implementing a complex narcotic regimen also contribute to inadequate pain control. Management of chronic cancer pain is similar to ischemic cardiac pain, in that both require the manipulation of multiple factors (Fig. 1). Hospice studies where aggressive pain management is practiced, have shown that in excess of

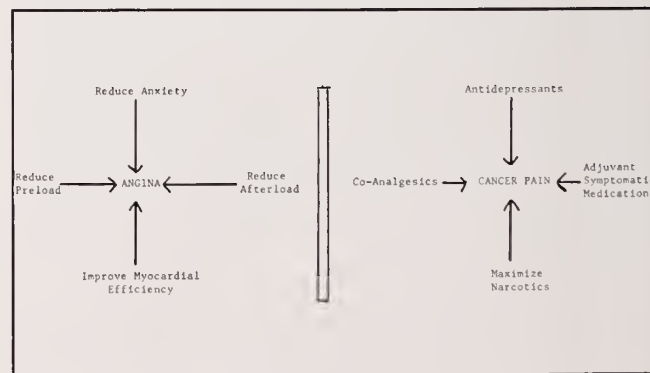


Figure 1. Analogy of chronic cancer to acute myocardial pain management.

*Medical Director, Department of Radiation Oncology, Southeast Alabama Medical Center Dothan, AL 36302.

TABLE 1
Nsaid for Bone Metastasis

INITIAL:

Ibuprofen (Motrin) 400 mg., po QID
Naproxen (Naprosyn) 375-500 mg., po 8-12 hr.
Diflunisal (Dolobid) 400 mg., po 8-12 hr.

REFRACTORY:

Indomethacin (Indocin) 50 mg., po q 6-8 hr.

BLEEDING RISK:

Choline Mg-Trisalcylate (Trilisate) 1 gm., po BID

TABLE 2
Short Duration Narcotics

<i>Pain</i>	<i>Analgesic</i>	<i>Four Hour Dose</i>
Moderate	Codeine (Tylenol #3)	60 mg. (2 tablets)
Severe	Oxycodone (Percodan, Percocet, Tylox)	10 mg. (2 tablets)
Excrutiating	Hydromorphone (Dilaudid)	4-40 mg.

90% of patients can be rendered painfree until death. An aggressive regimen typically requires a complex pharmacologic approach. To improve compliance it is important to explain clearly, to the patient and family, the rationale for and frequency of administration for each drug used.

General Analgesic Principles

The most important concept in prescribing narcotics for chronic cancer pain is that there is *no optimal or maximal dose*. The physician should start at the recommended dose and titrate upward until the patient is comfortable or unmanageable side effects occur.⁴ The oral route is always preferable as it is easier for chronic administration by the patient and family and will allow the majority of patients to remain at home until the terminal phase of their illness. Avoid PRN dosing and instead utilize an around-the-clock schedule. This results in better pain control and avoids agitation and anger by the patient when there is delay in receiving their prescribed narcotic during an acute exacerbation of discomfort.⁵ This also allows the physician greater accuracy in titrating the daily narcotic requirement necessary for relief.

A frequently encountered pain syndrome is metastatic bone disease. In addition to a narcotic, non-steroidal anti-inflammatory agents are of value by eliminating the prostaglandin component of bone pain. Table 1 is a listing of commonly used non-steroidals and their recommended dosing schedule. In patients who have thrombocytopenia or other factors placing them at risk for hemorrhage, I utilize Trilisate, which reportedly does not result in platelet dysfunction.⁴

Narcotic Usage

When trying to determine an appropriate narcotic for a patient, I group the narcotics into two categories, those with a short duration of action, generally in the range of 4-6 hours, and those with a longer acting duration, typically 8-12 hours. Among the short acting narcotics, I avoid Demerol, which although excellent for acute pain, when used on a frequent basis in high

doses over a prolonged period, can lead to CNS dysfunction and even seizure activity as a result of its metabolite Normeperidine.⁶ Table 2 lists the more frequently used short acting narcotics, all of which are excellent.⁷

A word of caution concerning the potential morbidity of the combination Oxycodone preparations. Percodan contains 5 mg. of Oxycodone and 325 mg. of Aspirin. Percocet contains 5 mg. of Oxycodone and 325 mg. of Acetaminophen, whereas Tylox contains the same Oxycodone with 500 mg. of Acetaminophen. The choice of these three medications is usually determined by whether there is potential morbidity with substantial Aspirin or Acetaminophen usage. If the non-steroidal anti-inflammatory effect of Aspirin is not needed, I then prefer Percocet due to its lower quantity of Acetaminophen.

When prolonged narcotic usage is anticipated, I attempt to convert the patient to a long acting narcotic regimen. The 8-12 hour dosing regimen allows for greater simplicity and increased compliance. My preference is either M.S. Contin or Roxanol. Either are well tolerated and easy to administer. M.S. Contin comes in a small, 30 mg. tablet. Roxanol comes in both, tablet and liquid form. Typically, a patient can be maintained on 30 to 60 mg. of M.S. Contin or Roxanol, two or three times a day, supplementing acute episodes of pain with a short acting narcotic.

I have had little success with Methadone, which has a complex pharmacology. The half life for excretion of its metabolite averages approximately 22 hours, while the analgesic effect is in the range of 6-8 hours. Therefore, in patients in which I have tried Methadone, I have experienced oversedation and confusion prior to obtaining good analgesia.

Adjuvant Meds

With substantial narcotics, patients will experience significant constipation, a major source of distress. This can be prevented by starting patients early on a stool softener and proceeding as necessary to more

TABLE 3
Management of Narcotic Induced Constipation

STOOL SOFTENER
SENOKOT — 2-3 q h.s. up to 2-4 tabs QID
DULCOLAX — 10-15 mg., q h.s. to 15 mg. TID
MOM — 30 cc. BID
ENEMA

aggressive laxative therapy. An outline of management is listed in Table 3.

As many as 40% of patients on narcotics will experience nausea as a result of chemoreceptor zone stimulation or reduced intestinal motility. If the nausea is felt to be CNS related, then either Compazine or Haldol are of value. If their nausea is felt to be a function of reduced intestinal motility, then Reglan is of benefit.

Longstanding, chronic pain results in depression, a condition which is known to lower the pain threshold.

Frequently, patients will respond to a low dose Tricyclic anti-depressant, such as Elavil 25-50 mg., q h.s.

As can be seen, aggressive pain management is complex, requiring the physician to constantly reassess the patient's response, adjusting the medications as necessary. However, the majority of patients can be rendered pain free, allowing them to remain relatively independent reducing the burden of their care until the terminal phase of their illness. □

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Status Report: Family Practice Obstetrics In Alabama — More Bad News

William J. Crump, M.D.*

A survey reported in *Alabama Medicine* in May 1986 revealed that of Alabama Academy of Family Physicians members, only 70 intended to continue to provide obstetrical services. Of this number, 10 were full time faculty members with residency programs. Since that time, a considerable shift in state political forces has resulted in passage of tort reform legislation intended to alleviate the burden of liability premium costs associated with family practice obstetrics. As yet, no moderation in premium increase has reached the individual physician.

In the two years since the last survey, more family physicians have ceased providing obstetrical care than expected. The purpose of this study was to quantify this process, and describe the geographic distribution of those physicians involved.

Methods

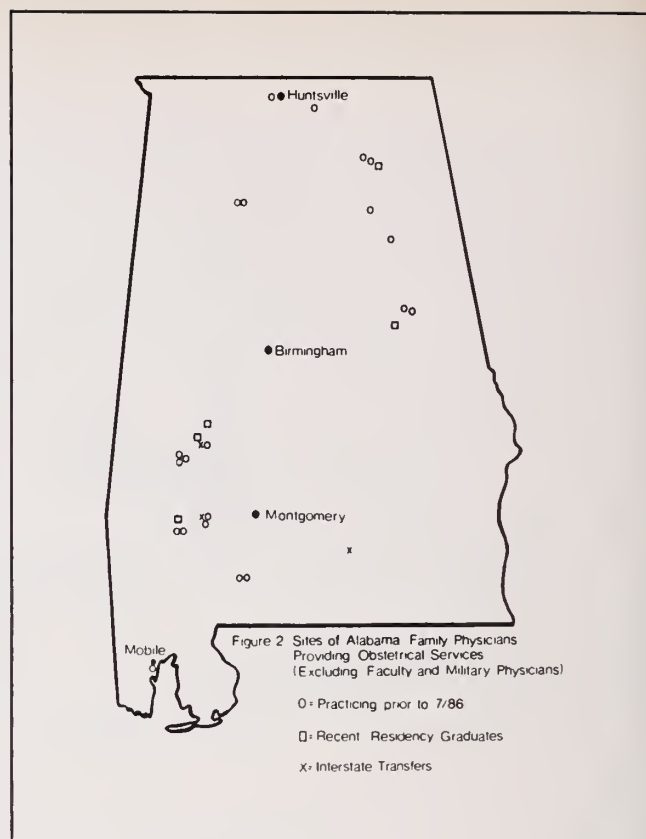
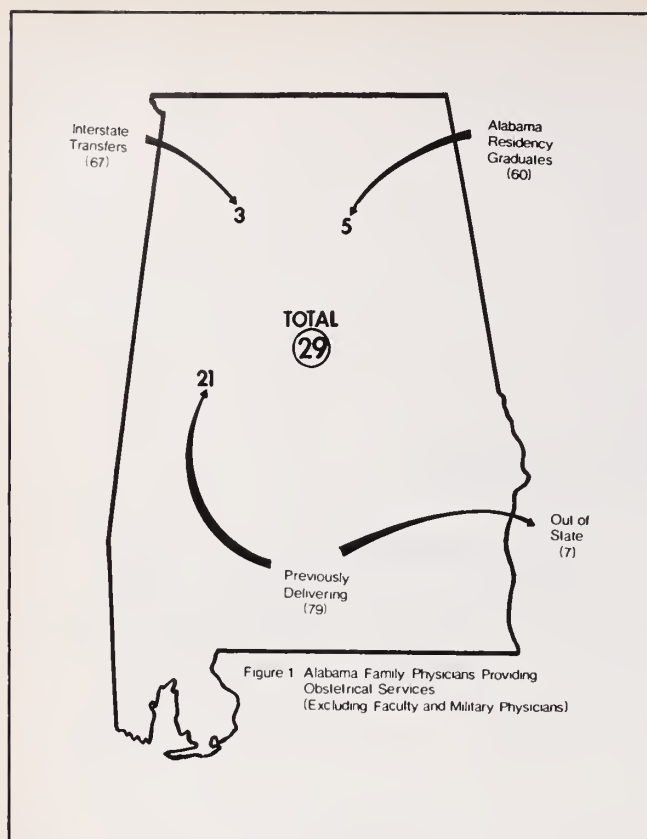
In October 1985 and January 1986, a survey was mailed to all 528 members of the Alabama Chapter of

the American Academy of Family Physicians concerning their current obstetrical care. With an 84% return rate, this survey identified 89 family physicians who were delivering babies. A repeat survey of these 89 was conducted by the Academy in October 1987, asking only whether they continue obstetrics. Also included in the survey were the 67 family physicians who moved into Alabama after October 1985, and the 60 family practice residents who graduated from Alabama programs in 1986 or 1987 and stayed in the state to practice. With the exception of one residency graduate, all of those contacted responded, for a sample of 215.

Results

Of the initial group of 89, 10 were full time faculty members with residency programs. Of the 79 family physicians in practice, 7 had moved out of Alabama, and only 21 continued to provide obstetrical care (Figure 1). Three of the 67 family physicians moving into Alabama deliver babies, and 5 of the 60 recent residency graduates include obstetrics in their practice, giving a total of 29. Not reflected in these results are

*Associate Professor, Family Medicine, University of Alabama in Huntsville, School of Primary Medical Care, 201 Governors Drive, S.W., Huntsville, AL 35801.



the 18 family practice faculty members who continue to deliver, including 7 in Huntsville, 5 in Mobile, 5 in Birmingham, and 1 in Tuscaloosa.

Figure 2 shows the geographic distribution of the private practice family physicians continuing to provide obstetrical services, with clustering in a few regional centers.

Discussion

The 1986 survey of this group of physicians identified 60 in private practice who would continue to provide obstetrical care. The majority of the physicians who had given up this part of their practice cited problems with medical liability risk or excessive premium cost as the reason.¹ The exodus from family practice obstetrics in Alabama is continuing, with no end in sight. It would be expected, and some say advantageous, for the occasional practitioner of obstetrics (less than 10-15 deliveries per year) to stop in the current situation. It would also be expected that older physicians might stop earlier than they had planned. However, there is no one to replace them. Only 8% of the recent residency graduates staying in Alabama included obstetrics, with most of those intending to pro-

vide this service leaving the state. The future doesn't look any brighter. A recent "straw poll" at the Huntsville program showed that while they were senior medical students making their future practice plans, 72% of the current residents thought they would eventually include obstetrics. Now that they are actually involved in their residency training, only 31% still had this intention. Two-thirds of those residents in training still committed to obstetrics planned to practice outside of Alabama. The result is that productivity and influx cannot keep up with attrition, creating a serious medical manpower problem.

When liability premiums for family physicians began to skyrocket in 1985, some observers welcomed the departure of physicians not trained in modern obstetrics. However, the process has now gone much further. A regional network of family physicians, representative of the statewide population, has reported their obstetric cases as the Alabama Perinatal Outcome Project (APOP).² There have now been several reports of their care published, demonstrating high quality outcome, sometimes with lower intervention rates than reported from teaching hospitals.^{3, 4, 5} At a recent national meeting, this network was recognized as a model most of the APOP participants have given up obstet-

rics, suggesting that we have "thrown out the baby with the bathwater."

Other regions have recognized the threat to quality care that the loss of family practice obstetrics presents. A model program was recently published from Beaverhead County in Montana.⁷ When the attrition process began there, a group of concerned family physicians, nurses, and hospital administrators attacked the issue head-on. The largest issue, in Montana as in Alabama, was lack of public concern. However, an initial community survey indicated that over 90% wished to maintain obstetric services in their area. A carefully planned community forum then addressed the problem as one of access to care by women in rural areas. The economic loss to the local community was also discussed. In one very small hospital, \$200,000.00 was lost in direct income for obstetrics and another 45% of pediatric volume was lost when the local family physicians gave up obstetrics. They also found that every dollar spent on medical care outside the community carried four other dollars with it. These facts make the case strongly for some kind of local subsidy to lessen the impact of increasing liability premiums.

Is family practice obstetrics in Alabama worth saving? The next few years hold the answer. From the map, it is clear that there are regional clusters of active physicians who for reasons of personal commitment or local particulars continue to provide obstetrical care. A logical plan would be to support these groups by a combination of state and local funds. This would provide access to low income mothers, while allowing the physicians to continue to deliver for local insured families, keeping local funds flowing through our small hospitals. Well trained future partners must also continue to be available to these physicians. Instead of graduating 20 family practice residents each year trained

in obstetrics as our state did in 1983, we may now only need 5-10 to fill spots in these regional centers. Economics will dictate whether new centers can be re-developed and if the production of obstetric-trained family physicians will need to be increased in the future. In the same straw poll in Huntsville, nine more residents indicated that they would choose to include obstetrics in their Alabama practice if they received financial assistance with the liability premium in return for caring for indigent patients.

The overwhelming problem now is apathy. If community family practice obstetrics is important, the leadership must come from the communities themselves. The Beaverhead County program is a blueprint for success, but it requires a small nucleus of motivated people to make it work. Is anybody out there listening? □

Acknowledgement

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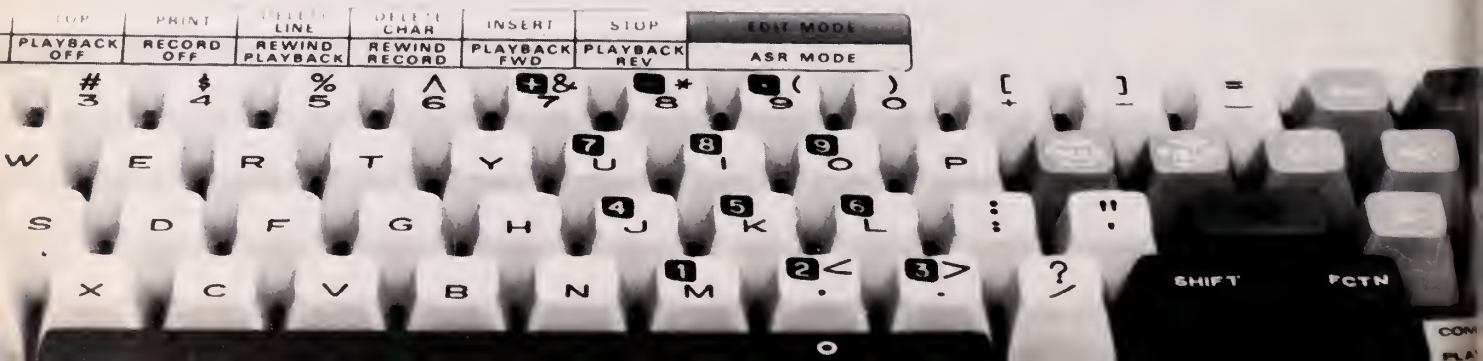
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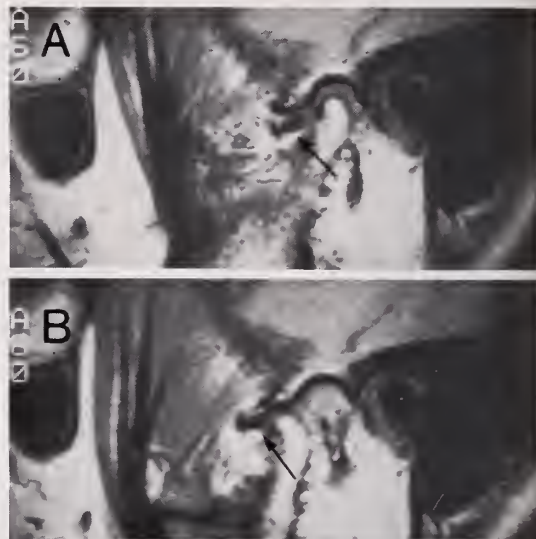
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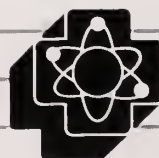


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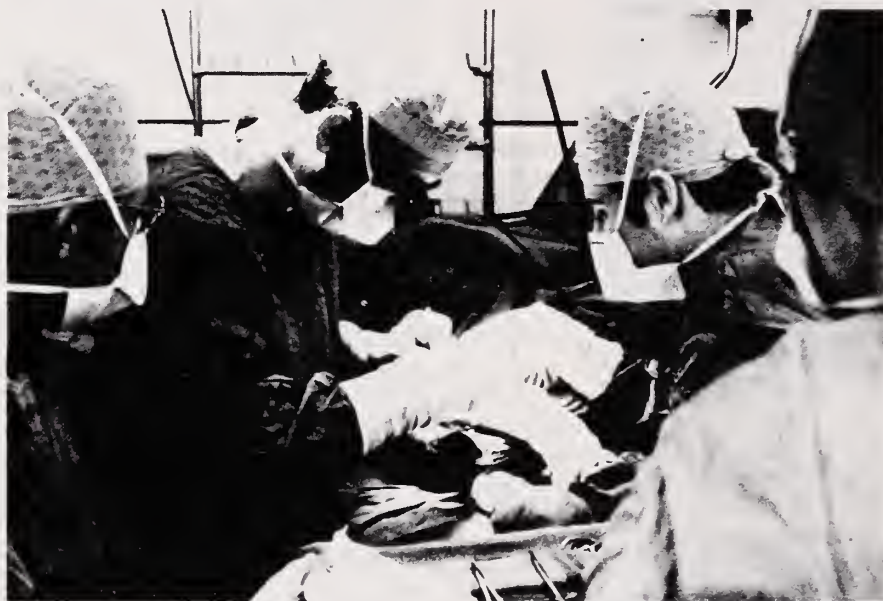
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When I think about the great ongoing projects of our auxiliaries and recognize the many critical problems that are being faced by our spouses and our communities, I realize the tremendous challenge that lies ahead for us. Our reputation of success and achievement and the potential for recruiting additional outstanding auxiliaries assures me that we can rise to the challenge.

At Decatur's Alabama Jubilee every Memorial Day there is a hot air balloon race. The beauty and grace of these balloons create such a majestic sight for the community and such a unique view for those who pilot the balloons, it is a favorite event. When I think about our coming year, I naturally hope that the communities will look up to our projects and that we shall have a

special insight into the problems of our state. That is when it occurred to me that the balloon would symbolize these wishes. Sometimes we have to rise above the problems to see the challenge.

As we move across the beauty of our state we see many challenges that are extending their hands toward us.

We see the couple that goes through the joys and chores of raising their children and as they prepare to love and have fun with their grandchildren they are confronted with the sadness and confinement of attempts to manage a parent who has Alzheimer's. They need guidance in their efforts, information on what to expect, and support in their struggle. Who's going to help them?

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The winds of change sweep us into the waste and destruction of the malpractice storm. We've moved from the dark clouds of despair and can now see rays of hope through the hard-earned laws of tort reform. However, if we want fairer sailing ahead we need the guardianship of justices on our Supreme Court who will insist that fairness prevail for both patient and physician. How are we going to improve the climate

in the coming election? We must get involved and know the candidates so that we can campaign for the best ones.

From our vantage point we look down into the jungle of ignorance and watch our youth struggling to escape their fear of AIDS. This fear is justified because there are so many people with AIDS in their early twenty's and they had to have come in contact with the virus while a teenager since the length of the incubation period average is two to seven years. There is a great challenge to get them the facts so they will know how to take care of themselves. Our AMA Auxiliary has outlined steps to take to inform our teenagers. This we must do before it is too late.

While AIDS gets our attention with fear and death, we must not forget that cigarette smoking is the number one preventable cause of death in the United States. Not only does it cause us to have smaller babies but it brings on shortened work life, long hospitalization and increasing cancer in women. One in five high school seniors smoke. The earlier people start smoking, the harder it is to quit later in life. This is one fire we need to fight.

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Although we have done so much, many problems remain to challenge us. We can't let our heads get in the clouds but we have to keep a clear view of what's happening across our county, state and nation. Let us RISE TO THE CHALLENGE.

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Symptomatic response to 'Tagamet' therapy does not preclude the presence of a gastric malignancy. There have been rare reports of transient healing of gastric ulcers despite subsequently documented malignancy.

Reversible confusional states have been reported on occasion, predominantly in severely ill patients.

'Tagamet' has been reported to reduce the hepatic metabolism of warfarin-type anticoagulants, phenytoin, propranolol, chlorthalidone, diazepam, lidocaine, theophylline and metronidazole. Clinically significant effects have been reported with the warfarin anticoagulants; therefore, close monitoring of prothrombin time is recommended, and adjustment of the anticoagulant dose may be necessary when 'Tagamet' is administered concomitantly. Interaction with phenytoin, lidocaine and theophylline has also been reported to produce adverse clinical effects.

However, a crossover study in healthy subjects receiving either 'Tagamet' 300 mg. q.i.d. or 800 mg. h.s. concomitantly with a 300 mg. b.i.d. dosage of theophylline (Theo-Dur®, Key Pharmaceuticals, Inc.),

demonstrated less alteration in steady-state theophylline peak serum levels with the 800 mg. h.s. regimen, particularly in subjects aged 54 years and older. Data beyond ten days are not available. [Note: All patients receiving theophylline should be monitored appropriately, regardless of concomitant drug therapy.]

Lack of experience to date precludes recommending 'Tagamet' for use in pregnant patients, women of childbearing potential, nursing mothers or children under 16 unless anticipated benefits outweigh potential risks; generally, nursing should not be undertaken in patients taking the drug since cimetidine is secreted in human milk.

Adverse Reactions: Diarrhea, dizziness, somnolence, headache, rash. Reversible arthralgia, myalgia and exacerbation of joint symptoms in patients with preexisting arthritis have been reported. Reversible confusional states (e.g., mental confusion, agitation, psychosis, depression, anxiety, hallucinations, disorientation), predominantly in severely ill patients, have been reported. Gynecomastia and reversible impotence in patients with pathological hypersecretory disorders receiving 'Tagamet', particularly in high doses, for at least 12 months, have been reported. Reversible alopecia has been reported very rarely. Decreased white blood cell counts in 'Tagamet'-treated patients (approximately 1 per 100,000 patients), including agranulocytosis (approximately 3 per million patients), have been reported, including a few reports of recurrence on rechallenge. Most of these reports were in patients who had serious concomitant illnesses and received drugs and/or treatment known to produce neutropenia. Thrombocytopenia (approximately 3 per million patients) and a few cases of aplastic anemia have also been reported. Increased serum transaminase and creatinine, as well as rare cases of fever, interstitial nephritis, urinary retention, pancreatitis and allergic reactions, including hypersensitivity vasculitis, have been reported. Reversible adverse hepatic effects, cholestatic or mixed cholestatic-hepatocellular in nature, have been reported rarely. Because of the predominance of cholestatic features, severe parenchymal injury is considered highly unlikely.

A single case of biopsy-proven periportal hepatic fibrosis in a patient receiving 'Tagamet' has been reported.

How Supplied: Tablets: 200 mg. tablets in bottles of 100; 300 mg. tablets in bottles of 100 and Single Unit Packages of 100 (intended for institutional use only); 400 mg. tablets in bottles of 60 and Single Unit Packages of 100 (intended for institutional use only), and 800 mg. Tiltab® tablets in bottles of 30 and Single Unit Packages of 100 (intended for institutional use only).

Liquid: 300 mg./5 ml., in 8 fl. oz. (237 ml.) amber glass bottles and in single-dose units (300 mg./5 ml.), in packages of 10 (intended for institutional use only).

Injection:

Vials: 300 mg./2 ml. in single-dose vials, in packages of 10 and 30, and in 8 ml. multiple-dose vials, in packages of 10 and 25.

Prefilled Syringes: 300 mg./2 ml. in single-dose prefilled disposable syringes.

Plastic Containers: 300 mg. in 50 ml. of 0.9% Sodium Chloride in single-dose plastic containers, in packages of 4 units. No preservative has been added.

ADD-Vantage® Vials: 300 mg./2 ml. in single-dose. ADD-Vantage® Vials, in packages of 25.

Exposure of the premixed product to excessive heat should be avoided. It is recommended the product be stored at controlled room temperature. Brief exposure up to 40°C does not adversely affect the premixed product.

'Tagamet' HCl (brand of cimetidine hydrochloride) injection premixed in single-dose plastic containers is manufactured for SK&F Lab Co. by Travenol Laboratories, Inc., Deerfield, IL 60015.

* ADD-Vantage® is a trademark of Abbott Laboratories.

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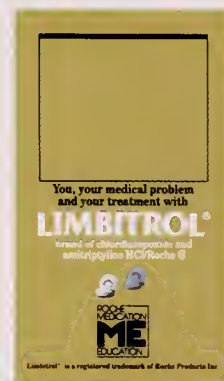
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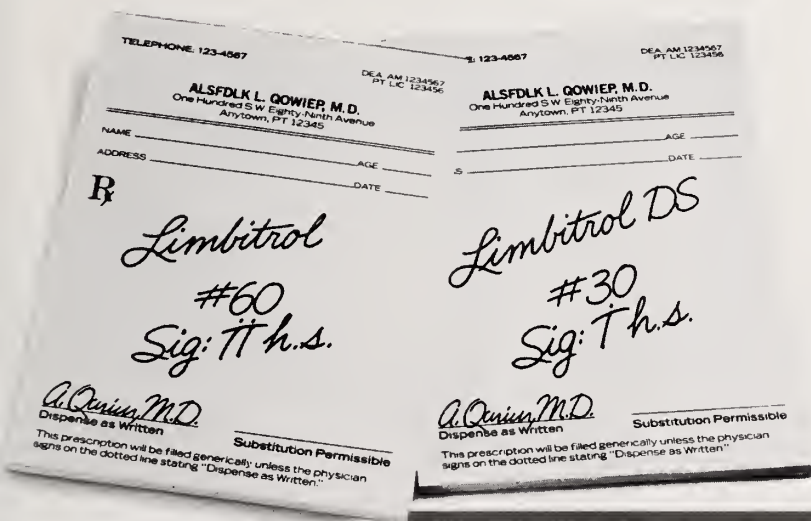
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References: 1. Data on file, Hoffmann-La Roche Inc., Nutley, NJ. 2. Feighner VP, et al: *Psychopharmacology* 61:217-225, Mar 22, 1979.

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Tranquilizer—Antidepressant

Before prescribing, please consult complete product information, a summary of which follows:

Contraindications: Known hypersensitivity to benzodiazepines or tricyclic antidepressants; concomitant use with MAOIs or within 14 days of monoamine oxidase inhibitors (then initiate cautiously, gradually increasing dosage until optimal response is achieved); during acute recovery phase following myocardial infarction.

Warnings: Use with caution in patients with history of urinary retention or angle-closure glaucoma. Severe constipation may occur when used with anticholinergics. Closely supervise cardiovascular patients. Arrhythmias, sinus tachycardia, prolongation of conduction time, myocardial infarction and stroke reported with tricyclic antidepressants, especially in high doses. Caution patients about possible combined effects with alcohol and other CNS depressants and against hazardous occupations requiring complete mental alertness (e.g., operating machinery, driving).

Usage in Pregnancy: Use of minor tranquilizers during the first trimester should almost always be avoided because of increased risk of congenital malformations. Consider possibility of pregnancy when instituting therapy.

Withdrawal symptoms of the barbiturate type have occurred after discontinuation of benzodiazepines (see Drug Abuse and Dependence).

Precautions: Use cautiously in patients with a history of seizures, in hyperthyroid patients, those on thyroid medication, patients with impaired renal or hepatic function. Because of suicidal ideation in depressed patients, do not permit easy access to large quantities of drug. Periodic liver function tests and blood counts recommended during prolonged treatment. Amitriptyline may block action of guanethidine or similar antihypertensives. When tricyclic antidepressants are used concomitantly with cimetidine (Tagamet), clinically significant effects have been reported involving delayed elimination and increasing steady-state concentrations of the tricyclic drugs. Use of Limbitrol with other psychotropic drugs has not been evaluated; sedative effects may be additive. Discontinue several days before surgery. Limit concomitant administration of ECT to essential treatment. See Warnings for precautions about pregnancy. Should not be taken during the nursing period or by children under 12. In elderly and debilitated, limit to smallest effective dosage to preclude ataxia, oversedation, confusion or anticholinergic effects. Inform patients to consult physician before increasing dose or abruptly discontinuing this drug.

Adverse Reactions: Most frequent: drowsiness, dry mouth, constipation, blurred vision, dizziness, bloating. Less frequent: vivid dreams, impotence, tremor, confusion, nasal congestion. Rare: granulocytopenia, jaundice, hepatic dysfunction. Others: many symptoms associated with depression including anorexia, fatigue, weakness, restlessness, lethargy.

Adverse reactions not reported with Limbitrol but reported with one or both components or closely related drugs: **Cardiovascular:** Hypotension, hypertension, tachycardia, palpitations, myocardial infarction, arrhythmias, heart block, stroke. **Psychiatric:** Euphoria, apprehension, poor concentration, delusions, hallucinations, hypomania, increased or decreased libido. **Neurologic:** Incoordination, ataxia, numbness, tingling and paresthesias of the extremities, extrapyramidal symptoms, syncope, changes in EEG patterns. **Anticholinergic:** Disturbance of accommodation, paralytic ileus, urinary retention, dilatation of urinary tract. **Allergic:** Skin rash, urticaria, photosensitization, edema of face and tongue, pruritus. **Hematologic:** Bone marrow depression including agranulocytosis, eosinophilia, purpura, thrombocytopenia. **Gastrointestinal:** Nausea, epigastric distress, vomiting, anorexia, stomatitis, peculiar taste, diarrhea, black tongue. **Endocrine:** Testicular swelling, gynecomastia in the male, breast enlargement, galactorrhea and minor menstrual irregularities in the female, elevation and lowering of blood sugar levels, and syndrome of inappropriate ADH (antidiuretic hormone) secretion. **Other:** Headache, weight gain or loss, increased perspiration, urinary frequency, mydriasis, jaundice, alopecia, parotid swelling.

Drug Abuse and Dependence: Withdrawal symptoms similar to those noted with barbiturates and alcohol have occurred following abrupt discontinuance of chlordiazepoxide; more severe seen after excessive doses over extended periods; milder after taking continuously at therapeutic levels for several months. Withdrawal symptoms also reported with abrupt amitriptyline discontinuation. Therefore, after extended therapy, avoid abrupt discontinuation and taper dosage. Carefully supervise addiction-prone individuals because of predisposition to habituation and dependence.

Overdosage: Immediately hospitalize patient. Treat symptomatically and supportively. I.V. administration of 1 to 3 mg physostigmine salicylate may reverse symptoms of amitriptyline poisoning. See complete product information for manifestation and treatment.

How Supplied: Double strength (DS) Tablets, white, film-coated, each containing 10 mg chlordiazepoxide and 25 mg amitriptyline (as the hydrochloride salt), and Tablets, blue, film-coated, each containing 5 mg chlordiazepoxide and 12.5 mg amitriptyline (as the hydrochloride salt)—bottles of 100 and 500; Tel-E-Dose® packages of 100; Prescription Paks of 50.



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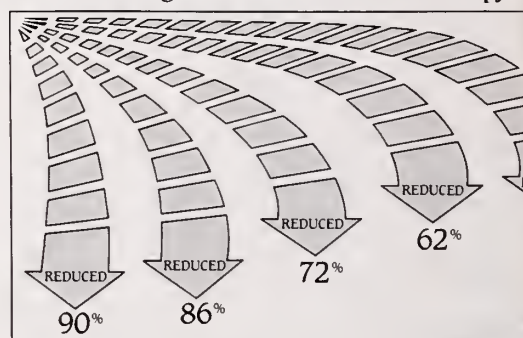
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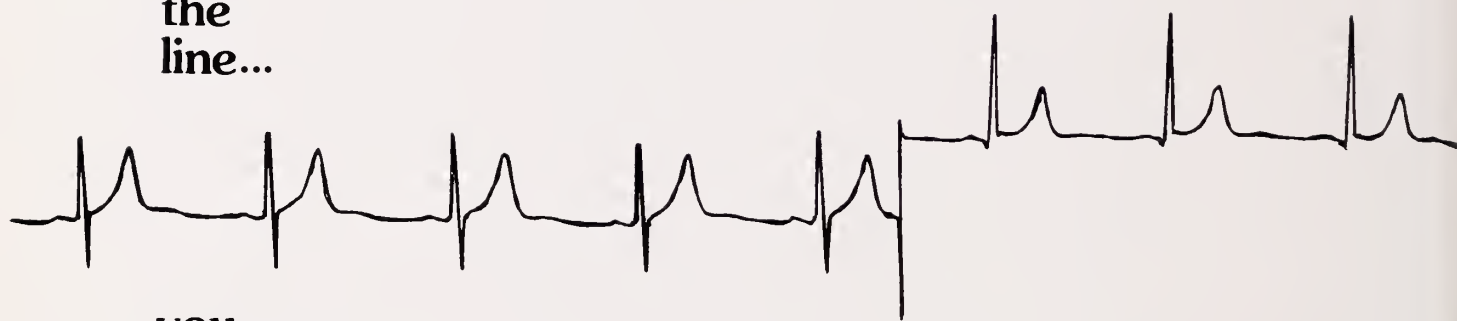
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Cover

The First Alabamians

"For some one hundred centuries, humans have inhabited the land now called Alabama. Primitive food grinding tools and stone points in Russell Cave in Northeastern Alabama attest that prehistoric men and women sought shelter in this huge, dry cavity eight to ten thousand years ago. . . ."

— Alabama Historian Virginia Van der Veer Hamilton,
in her book, *Alabama* (Norton, 1977)

On the cover is a detail from James Thomas Neumann's inaugural painting in the MASA-sponsored Alabama Heritage Collection. Limited-edition prints from the series will be offered to physicians first, then to the general public. The originals will remain the property of the Association, with permission to be granted for legitimate use in textbooks, state tourist promotion, and by scholars.

Among those early Alabamians depicted on the cover was surely a medicine man or two, Alabama's first doctors. In common with all ancient cultures, writes Temple University Historian Roderick McGrew in his *Encyclopedia of Medical History* (McGraw-Hill 1985), American Indian civilizations, early and late, combined medicine and religion: "Priests, shamans, medicine men or sorcerers were entrusted with the rituals which served as a basis for diagnosis and cure. Supernatural agencies were believed to cause illness, often as punishment for human error or misbehavior. . . ."

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CODEINE	X	X	X	X	X
OXYCODONE	XX	XX	XX	XX	XX

Blank space indicates that no such activity has been reported.

Table adapted from Facts and Comparisons (Nov.) 1984 and Catalano RB. The medical approach to management of pain caused by cancer. "Semin Oncol" 1975; 2; 379-92 and Reuler JB, et. al. The chronic pain syndrome: misconceptions and management. "Ann Intern Med" 1980; 93; 588-96.

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Respiratory Depression: At high doses or in sensitive patients, hydrocodone may produce dose-related respiratory depression by acting directly on brain stem respiratory centers. Hydrocodone also affects centers that control respiratory rhythm, and may produce irregular and periodic breathing.

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PRECAUTIONS:

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Information For Patients: VICODIN, like all narcotics, may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery; patients should be cautioned accordingly.

Cough Reflex: Hydrocodone suppresses the cough reflex; caution should be exercised when VICODIN is used postoperatively and in patients with pulmonary disease.

Drug Interactions: The CNS-depressant effects of VICODIN may be additive with that of other CNS depressants. When combined therapy is contemplated, the dose of one or both agents should be reduced. The use of MAO inhibitors or tricyclic antidepressants with hydrocodone preparations may increase the effect of either the antidepressant or hydrocodone. The concurrent use of anticholinergics with hydrocodone may produce paralytic ileus.

Usage in Pregnancy: Pregnancy Category C. Hydrocodone has been shown to be teratogenic in hamsters when given in doses 700 times the human dose. There are no adequate and well-controlled studies in pregnant women. VICODIN should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nonteratogenic Effects: Babies born to mothers who have been taking opioids regularly prior to delivery will be physically dependent. The intensity of the syndrome does not always correlate with the duration of maternal opioid use or dose.

Labor and Delivery: Administration of VICODIN to the mother shortly before delivery may result in some degree of respiratory depression in the newborn, especially if higher doses are used.

Nursing Mothers: It is not known whether this drug is excreted in human milk; therefore, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS:

Central Nervous System: Sedation, drowsiness, mental clouding, lethargy, impairment of mental and physical performance, anxiety, fear, dysphoria, dizziness, psychic dependence, mood changes.

Gastrointestinal System: Nausea and vomiting may occur; they are more frequent in ambulatory than in recumbent patients. Prolonged administration of VICODIN may produce constipation.

Genitourinary System: Ureteral spasm, spasm of vesical sphincters and urinary retention have been reported.

Respiratory Depression: (See WARNINGS.)

DOSAGE AND ADMINISTRATION: Dosage should be adjusted according to the severity of the pain and the response of the patient. However, tolerance to hydrocodone can develop with continued use, and the incidence of untoward effects is dose related.

The usual dose is one tablet every six hours as needed for pain. (If necessary, this dose may be repeated at four-hour intervals.) In cases of more severe pain, two tablets every six hours (up to eight tablets in 24 hours) may be required.

Revised, April 1982.

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1. Hopkinson JH III: *Curr Ther Res* 24: 503-516, 1978
2. Beaver, WT *Arch Intern Med*, 141:293-300, 1981.

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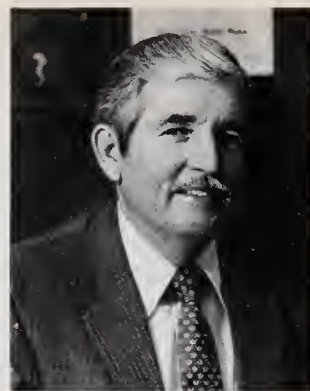
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S. Lon Conner
Executive Director, MASA

Only Yesterday

There is nothing magic about decades and centuries; they simply give us convenient compass points for arbitrary comparisons.

Even so, looking back can always be instructive, as I think you will see by reading the eloquent Annual Oration (reprinted in this issue) by Benjamin James Baldwin, M.D., of Montgomery, before the annual session of MASA in April 1888, an even century ago.

Dr. Baldwin's public speech, the predecessor I believe of the Jerome Cochran lecture, was praised by *The Montgomery Advertiser* for its inspiration and daring. Dr. Baldwin proposed some innovative ideas for health education, which subsequently became law.

Reading through *Transactions 1888* in which this speech is recorded, I noticed with interest that physicians were deeply concerned about sexually transmitted diseases as well as the still unanswered mysteries of yellow fever and the like.

Reading through the reports of the individual county societies I was struck by some similarities and some differences between 1888 and 1988. Then as now, Jefferson County had the largest enrollment of members, 55. But, curiously, Wilcox County then had as many members, 32, as Montgomery, and more than Mobile (25) or Madison (22). That probably says something about the decline of the cotton kingdom since 1888.

The 847 members reported by the constituent societies represented about 60% of the known practitioners in the state at that time. Today, of course, we do much better.

There was an "omnibus discussion" of what appeared to be a new hybrid disease, typho-malarial fever, although some dissidents questioned its existence

as a separate disease process from typhoid or malaria. A major topic of discussion in 1888, just as today with Medicare, was "The Medical Treatment of Old Age," the *Transactions* account of the discussion opening in this fashion:

"Our text books contain elaborate instructions in regard to the therapeutics of infancy and adolescence, but are almost silent touching the medical treatment of old age. . . . Pneumonia occurring in the young and vigorous is successfully treated by antiphlogistic means, blood letting, veratrum, antipyretics, etc., but the same disease in the aged is so modified by reason of devitalizing influences that all lowering agents are *contra* indicated. . . ."

Prostate problems and the rheumatic diseases were at the heart of some of the discussions. The more things change the more they are the same.

The same feeling of *deja vu* occurred when I looked up some of the events of the world at large for 1888. Can you believe that the principal issue in the presidential campaign of 1888, as so far in 1988, was the question of foreign competition and the impact of imports of American industry? Democrats wanted to raise tariffs; Republicans were opposed.

The presidential election itself was a rather strange one, but perhaps it had analogues for our time as well. The incumbent President, Grover Cleveland, Democrat, had acquiesced in offering for re-election, but he said he would not deign to campaign for the office. It would be undignified, he said, for a sitting President to hit the hustings and ask for votes.

The Republican candidate 100 years ago was Benjamin Harrison. Harrison said that if Cleveland wouldn't take to the campaign trail, neither would he. He invited

the folks to come to his Ohio home and hear him orate from his front porch. Republicans organized trainloads of supporters to do just that. Harrison's front porch campaign drew crowds as large as 300,000, while President Cleveland sulked in his tent.

Harrison, it seems scarcely necessary to add, unseated Cleveland in the election.

As it happened, 1888 was the first year that the Australian secret ballot was used in this country — Louisville, Kentucky, having that distinction. You may be interested to know that the last state to adopt the secret ballot was South Carolina in 1950, less than 40 years ago.

About the time our predecessors were meeting here in Montgomery, George Eastman was about to make a profound change on our society, although no one knew that at the time. He introduced the "Kodak box camera." Less well known but even more profound was the invention by Tesla that year of the alternating current motor.

Jim Thorpe, called by some the greatest athlete of all time, was born in 1888. And that was the year Jack the Ripper murdered six women in London. The world's first beauty pageant was held that year, but not, as you might have guessed, in the United States. Belgium started it all in the city of Spa.

Even the television that now fills too much of our lives was prefigured in 1888: Heinrich Hertz (whom we honor with kilohertz and megahertz) identified radio waves as belonging to the same family as light waves.

Medical history, like the rest of human history, is thus a continuum. Dip in anywhere in the past and it is easy to see that today's concerns are different only in external shape: to your professional antecedents meeting in Montgomery in 1888 syphilis was every bit as disturbing to them as AIDS today.

In one aspect of this brief flashback to a century ago I think mankind has gone downhill. I would like to see a return to the Harrison front porch campaign for president, whereby the candidates would announce that anyone who wanted to hear their vaporous offerings could come to their front yard.

The point of all this is that while problems ebb and flow, the fundamental challenges to medicine seem to remain constant over the decades. ■

Lon

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President, MASA

On Being Indispensable

Woodrow Wilson in 1912 and Franklin Roosevelt 20 years later both paid lip service to this statement: "There is no indispensable man."

History reveals that neither believed it. When President Wilson said it, he was sick and partly paralyzed but determined to run the country regardless.

Roosevelt was running for his first term when he repeated the statement in 1932. But evidence of his apparent conviction that the statement didn't apply to *him* was his later running for unprecedented third and fourth terms.

In other words, the false modesty of decorum dictates that we all deny our indispensability. As long as physicians understand that it is only a ritual disavowal, fine. But it is my belief that it is every physician's *duty* to make himself indispensable: Indispensable to his patients; indispensable to his profession; indispensable to his community.

The first step toward indispensability is a self-awareness inventory. Ask yourself: "Am I really using all my talents in the most efficient way to make myself indispensable to my patients?"

Be honest in your answers. Then ask the same question of yourself regarding your profession and your community. Are you really giving the best that's in you? Tokenism won't cut the mustard. Both your patients and your peers will know it if the effort you offer is less than 100%.

There is an old Southern expression that speaks volumes on the observational acuity of ordinary people. "He gives every job a lick and a promise." In my childhood and perhaps yours, that was a devastating critique of half-hearted effort.

If you give less than your best to a patient, that patient will detect it and pass on the observation to others. If enough people in the community say it about

you, yours will not be an enviable image. If your peers reach the same conclusion, and they will if you make a habit of giving just enough to get by, it will be reflected in your referrals.

The same is true of your community participation. It is all-important, I believe, that physicians return to the days when they were indispensable to community leadership objectives. If you don't believe you owe your community anything beyond the pleasure of your company, very soon that community will show you it doesn't owe you anything.

All mutually advantageous relationships must be reciprocal. Just as there can be no unilateral friendships or unilateral marriages, so too must all relationships between the physician and his profession, and the physician and his community be bilateral.

When you go all-out for your patients, for your city or town, for your profession, you will be rewarded for your dedication. That's what the Bible means about casting your bread upon the waters.

These are homilies, but they are essential homilies we may have let fall into disuse. For most of the past two or three decades health care had been a seller's market. For the past few years it has been a buyer's market, the day of reckoning. The heady years of constant expansion are over, if not forever at least for the foreseeable future.

All those cracks and fissures you see about you are signs of imposed contraction, the inevitable consequence of unrealistic expectations exceeding resources.

But patients are being squeezed too, and they look to us for the best we can deliver under the constraints imposed on them and on us.

We *must* deliver, putting aside any animosity we may have for being made the villains. Patients didn't

bring this about; your community didn't; and certainly your profession didn't. Seek your revenge in being indispensable to your patient, your peers and your townspeople.

Don't get mad, the saying goes, get even. Get even with all our detractors by being unassailably thorough in the care you give, ignoring the fact that you will likely be underpaid. If money were the only compensation in medicine, how many of us would be in practice?

"Living well," the philosopher said, "is the best revenge." By living well I mean enjoying the full trust of your patients and your peers and finding total satisfaction in the art and science of your service as a physician. The gratitude and trust of patients are not rewards subject to anyone's prorating.

In an era when doctor-bashing has passed from the fashionable to idiotic triteness, we can best build our constituency by earning the fierce loyalty of our patients, a force that politicians and bureaucrats may challenge only at their extreme peril.

If we are indispensable to our patients, that armor will be ours. If we are indispensable to our profession and our communities, that strength is squared and cubed.

In the final analysis the most important wealth in this life is self-esteem. The truly indispensable man will give his maximum effort in everything he attempts, thus to earn for himself the one reward that can have no relative value scale, cannot be frozen, rolled back, pro-rated or discounted by any of the bean counters — his own measure of his worth.

Some may detect ambiguity or contradiction in my thesis that self-interest and virtuous conduct are the same, and that in them lie both the beauty and the collective power of our profession.

I rest my case with this brief passage from Samuel Taylor Coleridge 160 years ago:

"In all the outward relations of this life, in all our outward conduct and actions, both in what we should do and in what we should abstain from, the dictates of virtue are the very same with those of self-interest; tending to, though they do not proceed from, the same point."

Be indispensable to your patients, your colleagues, your townspeople, your legislators. But this above all: *be indispensable to yourself.*



Bill

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The Annual Oration for 1888



By Benjamin James Baldwin, M.D., of Montgomery,
Junior Counsellor, Medical Association of the State of Alabama
Presented in Montgomery April 1888

Ladies and Gentlemen:

The Association must be congratulated on the advent of another occasion which permits us to renew that "fraternity of intellect and sympathy of feeling which makes us one of another." What is truth for one is truth for all; therefore we have a common interest in the aims, purposes, developments and promotion of the Medical Association of the State of Alabama. The evaluation of the medical profession by the promotion

of honor, dignity and usefulness amongst its members; the development of science and the good of humanity, have been and will ever continue to be the objects of this body. To accomplish such commendable results, our members must be gathered from all parts of the State and united in one harmonious fraternity, and must adopt such measures as will promote and perpetuate among ourselves an *esprit de corps*, a conformity of

sentiment and feeling and a combination and cooperation in action. Any interested observer will cheerfully admit that the increased power, influence and importance of the Medical Association of the State of Alabama could only have been accomplished by the adoption and administration of some such wise, well regulated and systematic laws. Disavowing any forced sentiment, or over-drawn expressions of good will, I say, with all candor, that the Medical Association of the State of Alabama stands second to no medical organization among the English speaking people. I have lived a number of years among the medical bodies of the great State of New York. I have been a member of the medical association of the good old State of Kentucky; I have sat in the deliberation of medical societies in that gloomy old city on the Thames; but I have yet to see an organization of medical men whose deliberations are governed with more system and order, or whose laws are regulated with more wisdom and judgment than that of our own. Who is there that has observed through the past ten years, who can not see that the medical profession in this State has been moving onward and upward to a great awakening? We have advanced without a halt, and with an irresistible force, because the momentum is that of the great mass.

I willingly and gladly admit that to a few belong great praise. I cheerfully acknowledge that to one belongs the greatest praise, but at the same time, I declare that it is not alone a single leader or even a few who are kindling by their own enthusiasm a temporary blaze of interest, energy and excitement in the multitude; dragging them forward as with cords by their own strong zeal and energetic spirit; but it is the inborn determination, perseverance, fidelity and soul which is animating the mass, the carrying it forward in its legitimate course.

A pleasant meeting we had last year in that beautiful old town among the oaks, and profitable as well. There was an incident of that meeting, which has a special significance in this connection. Possibly there were five or six or more doctors who came great distances in their buggies, over rough mountainous roads to be with us in Tuscaloosa, but there was one who rode sixty odd miles on horse-back to have the honor of participating as a delegate in this Association.

Here is a tale with its lesson, and in future years you may build a monument as high as you please in honor of those to whom praise is due for setting this association on its successful career, but place here and there in the shaft a little tablet in honor of the brave, common sense, faithful country doctors who add so much to our strength, our influence, our honor and our usefulness. These are the men in greatest numbers here tonight. These are the men who leave the comforts of home and come by long and tiresome journeys from various and remote parts of the State to contribute to the success of our meetings. These are the men who

strengthen our power and without whom we could not so successfully thrive.

Now, Mr. President, the constitution of the Medical Association says "there shall be elected at every annual session an orator, whose duty it shall be to prepare and deliver a public address on some subject connected with medicine, or the medical profession." A public address is intended for a public audience, and that means a miscellaneous audience. Ah! it is infinitely hard to talk medicine to doctors, and at the same time be intelligent to the mass.

I propose, therefore, to address my remarks more particularly to the public on

Health, and Physical Education, as a Means of Promoting It.

Physiological observers tell us that the human race is deteriorating, physically, in all civilized quarters of the globe. It becomes then a question of wise political economy how to arrest this deterioration. People who live regularly, industriously, temperately, religiously, can well afford to be ignorant of the laws of health, and the precautions necessary to preserve it to modern lovers, for those who live naturally, nature is a self regulator; her instincts are a guide and safe guard as to health and disease. But, men and women whose lives are artificial must study how to preserve the health under such artificial environment, or the race will become in time extinct. To live to purpose, man should live long, and life should be cherished by all those practices which tend to keep it in its highest, healthiest forms, and to its greatest duration. Health is, therefore, a duty. When one gets sick, it is generally his own fault; the result of either ignorance or presumption, and the only remedy against the physical destruction of the race is to secure a practical intelligence of the laws of human life. Writings on health are among the oldest in the world, and the subject has engaged the attention of the profoundest thinkers, and the most renowned leaders of men. "The elaborate directions for the preservation of health found in the Mosaic laws show why the Jews enjoyed such an immunity from disease." Not only in mediæval and modern history, but even in our own time the Jews have been spared the ravages of epidemics when their Christian neighbors were perishing like insects around them. Eminent thinkers have attempted to explain this by saying that the periodical cleansing of their dwellings involved in the thorough search for the leaven which preceded the yearly passover, had a notable effect in preventing that continuous deposit of organic matter which is one of the most powerful factors in the production of disease.

Says Dr. Johnson: "It will hardly be contended that the prohibition of pork was a command from the Almighty for the salvation of a Hebrew's soul. But when it is recollected that leprosy was prevalent in Judea,

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and that swine were believed to be very much subject to that loathsome malady, the prohibition of pork may be easily accounted for. The sentence of uncleanness passed by Moses on so many beasts, birds and fishes is also inexplicable on any other supposition than that it was based on some sanitary code of diet. There can be little doubt that the minute regulations respecting diet, ablutions, etc., so rigidly enforced among the Hindoos, Egyptians and Greeks, were directed to the preservation of health, although under the form of religious ceremonies. The priests, who were the physicians, wisely concluded that injunctions would be better obeyed when they were affirmed to be mandates from Heaven than if they were considered as merely of human invention. It is lamentable but instructive to realize the difference between ancient and modern legislation on the subject of public health. Read the laws laid down by *Lycurgus* for the preservation of the health and the physical development of the Spartans. Read the regulations enjoined by *Brama*. Go back to the very foundation of the world and you will find the this subject was of the first importance among the rulers of nations. Then can you suppress the pangs of shame when you realize that the extent to which our national government goes in the protection of public health consists simply in removing a few nuisances, and establishing a nambypamby quarantine against even such plagues as cholera, which, when inclined, can leap over a triple cordon of Prussian bayonets with as much ease as a wolf enters the open door of a sheep-fold. In the matter of State legislation, we have reasons to congratulate Alabamians on the enactment of health laws which are far in advance of most of the other States. Indeed, very few States in the Union have made any efforts to shield their people from the invasion of disease.

Why is this? Is it simply because health is a negative quality and during the absence of disease the fortunate possessor never knows his happiness till it has gone? or is it that the mass of men do not appreciate it at its real value? Yet if you strike it out from the list of regal prerogatives the imperial diadem proves a crown of thorns, and without it the glittering symbols of ancestral pride and noble birth grow hateful to the eye.

Is health something you can buy? Can the "throbbings of a fevered brain be palliated by the embroidered pillow or the purple canopy?" Does not the grim monster demand from affluence an unconditional surrender of all the good things transmitted by heritage, acquired by industry, or accumulated by avarice? Can fame defy the stings of sickness, or power neutralize the agonies of pain? The renown of many a victory could not diffuse an anodyne influence over the pillow of Napoleon Bonaparte, and the laurels of Morengo did not defend him against the fogs of St. Helena.

Is there, then, no state or condition exempt from disease? Absolutely none!

Is there any remedy which can close the avenues of corporeal suffering? Absolutely none. Is there then any subject of greater importance or more worthy of consideration by the profoundest thinkers than that of health? Absolutely none. Why, then, is there such indifference, such gross carelessness, such culpable neglect, and such alarming ignorance on the part of the people as to the prevention of disease and preservation of health? For the simple reason that their early education has been shamefully neglected.

There is no question that the American people are pursuing a course in their own habits and practices, through ignorance of the laws of hygiene and physiology, which is destroying health and happiness to an alarming extent; and I think that I can show that the majority of the rising generation are being educated in a way that will encourage feebleness, deformity, homeliness, disease and misery. The anxious and fond parents eagerly provide a mind teacher for their children, sometimes at five and six years of age. Do they provide for physical development at the same time? Oh, no; but if we turn back the pages in the world's history we will find an important lesson bearing on this point. Some twenty centuries ago the Greeks were a small people occupying a small country, and yet they became the wisest and most powerful of all nations. They were remarkable, not only for their wisdom and strength, but for their great beauty, so that the statutes they made to resemble their own men and women have ever since been regarded as the most perfect forms of human beauty. Now the chief reason why they excelled all nations was the great care they took in educating their children. They had two kinds of schools, the one to train the minds, the other to train the bodies. And though they estimated very highly the education of the mind, they still valued the part of school training which tended to develop strong, healthy, graceful and beautiful bodies. Are not we pursuing a very different course? It is true a large portion of the American people are providing schools for educating the minds of their children, but instead of providing teachers to train the bodies of their offsprings, most of them have not only entirely neglected it, but are doing everything they can to make them feeble, sickly and ugly.

The American people seemingly do not believe that a full expansion of the corporal organs is essential to a complete development of the mental faculties. They ignore the fact that strength of mind must be intimately associated with strength of body. They smile carelessly when they are able to remember some great mind which has accidentally inhabited a feeble body, or some queer genius with a club foot or a crooked spine. And they revel further in this mock argument when they point you back to that cruel part of the sanitary code of *Lycurgus* which destroyed all Spartan children born with deformity or defect, and say that had Pope been born in Laconia, the poet of Twickenham would never

have "lisped in numbers" or tuned his lyre to the Rape of the Lock, or that had Byron even been a Spartan, Childe Harold would never have

"Passed the barren spot
Where sad Penelope o'erlooked the wave,
And onward viewed the mount not yet forgot,
The lover's refuge, and the Lesbian's grave."

Notwithstanding the stoical indifference of our people to the importance of physical training, the fact remains that rigid training of bodily powers among the ancients almost annihilated disease. But passing over the ordeals of the sanitary code of centuries ago, we come down to the facts which are readily acknowledged by all scientists, that systematic exercise of the physical powers is of far more importance in children up to certain ages, than is exercise of the mental powers. The influence of such systematic training on health and morals has been demonstrated to be absolutely astonishing, and it is contended that strenuous exercise and simple food will control the sympathies, affections and thoughts beyond all the precepts of priest or philosopher. The muscles of early youth are so imbued with an exuberance of vitality that quietude is irksome, and this exuberance is joyfully as well as profitably expended in an active exertion, if children are given an opportunity. But let me paint a picture of the ideal child of the present day:

(1) Here he is; the pet of the household, beautiful and gifted, with large eyes, long eye-lashes, well cut eye-brows, full lips, a beautiful complexion, fine silken hair and bright mind; such children are generally precocious and they should especially be held back in all mental training until their physical powers are well advanced. But how are they generally treated? Why, they are encouraged by ambitious parents to manifest their mental powers, which are often remarkable, and, I grant, very fascinating.

For a few years such children are looked upon with admiration and wonder. But the over stimulated nervous system has little resistive power, and having used their nerve force too freely, instead of storing it up, when the hour of trial comes, that force is spent which would have enabled them to weather the storm, and disease is quickly fatal.

Thus, the laurel is converted into the cypress to wave over the tomb of talent or over the living wreck of mind and body.

For a practical illustration of the injurious effect of too early and too much mental exercise in the young, let us compare the precocious child of the city with the dull one of the country.

(2) The little city urchin can see fifty mischiefs that would pass undiscovered by the dull rustic. But while the town child is living in excitement and using up his nerve force, the country child is developing a strong body and storing up his nerve force for future use, and

in the course of time will surpass the other in brain power. There is an old proverb which says:

"You can't eat cake and have it." Ah! I am afraid civilization is leading us too fast, for we can yet look back into the centuries that have rolled by and glean important facts in regard to mental and physical training.

Now, why do I direct your attention so particularly to the proper physical training of the young. You say there are the heads sprinkled with gray and white, but we can't change them, they are too far down the stream of life. Then there are those of middle age, healthy, strong, robust, but we can't change them; they think they will never need any information concerning health. Then there are young women, with sensitive nerves, susceptible feelings, exquisite sympathies, tender affections, delicate organizations, beautiful faces; reared like hot-house plants. I suppose they will continue to issue forth in the face of a driving blizzard, to the ball room, the opera or theatre, in a gossamer dress that might well suit the skies of the Sandwich Islands. The consequences are serious, but can you change them? Who will volunteer to try? Then there are the young men; well you may tell them about midnight hours at the club, tell them the fate of the gourmand and the bacchanal, but can you change them? Just as well whistle to the wind. Then the only chance for us is to begin at the first round of the ladder, the little child in the school room. Now, if we are going to accomplish anything, we must educate public opinion and look for results in the future. In common with all important reforms this can only be effected fully by securing the co-operation of those for whom the benefit is chiefly intended. I am aware that it is a difficult task to enlighten the mass on subjects which influence public health, hence the opposition of the illiterate to sanitary reform, and the indifference to hygienic improvements on the part of political boards. This, however, must be overcome, and in its place must be secured full appreciation of wise and liberal provisions for the development of strong and healthy bodies as well as strong and healthy minds.

Now I suggest, Mr. President, that this Association, whose influence is strengthened every day, take hold of this subject and advocate the adoption by the legislature of a bill introducing, wherever practicable, the subject of physiology, anatomy and hygiene in all the public schools of the State.

I am aware that there are pessimists who go on the theory that a little learning is a dangerous thing. They theorize further, and say that if you put physiology, anatomy and hygiene in the hands of the children you make them afraid of themselves; you make them prematurely old; you rob them of the freedom and pleasure of childish sports; you make them prudish. Ah! what nonsense. Just as well say that philosophy and physics

will make them infidels or that history and rhetoric will unfit them as men of business. Is it not far better for the people to know the laws of health and happiness, than it is for them to learn by bitter experience the result of ignorance of these laws, the subsequent suffering and unhappiness? Now while we are endeavoring to aid the coming generations to improve their physical as well as mental development, let us protect them until they have reached that point where they can protect themselves.

(3) And to this end let this Association advocate the introduction by law of adequate ventilating arrangements under the best plans and thorough supervision. Until school boards are educated to the true importance of a constant and wholesome exchange of atmosphere in the school room, it is useless to expect them to make the necessary outlay or arrangements which make no show and to them are of little value. Let there be systematic and compulsory hourly drills in gymnastics, calisthenics, military motions, etc., and the provisions of this character to be as minute and matured as those for mental development.

Require that the grading of seats and desks be adapted to the physical necessities and conditions of the child, and that the direction and quantity of light and color admitted into school rooms shall be controlled by the best known principles of optical hygiene. Provide time for a regular, deliberate and wholesome meal at noon, and for sufficient natural and stimulating exercise and amusement in stormy, as well as fair weather.

Some advance has been made in the Northern States in this department in the last ten years, and I trust that the next decade will witness a far more gratifying progress, and I hope that Alabama, which has shown so much wisdom in the enactment of sanitary laws, will be foremost in this important department of education.

I thank the good people who have so kindly given me their attention this evening, but I ask more than merely a respectful hearing; I have a right to ask it, to demand it; for, however feebly I plead the cause of the young, the innocent, the helpless, whom Gom has confided to us mind and body, this hour has been vain and unprofitable, if it leaves no fruit in action, for I have discussed no abstract question, I have advanced no theory of a doctrine, but in plain and wholly inadequate language, have tried to make clear the duty you owe to society and the State in the proper education of the children. It is the most sacred, the most stupendous obligation that is imposed upon the citizen of a free country. I shall not offend this intelligent audience by dwelling upon the necessity of a general education, of giving all classes an equal opportunity to breathe this breath of moral, spiritual and intellectual life upon which depend all peace and happiness, truth and justice, religion and piety for all generations. Self-preservation alone compels a liberal, fostering care of



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A daily prophylactic dose in a single tablet.

Please see next page for brief summary of prescribing information.

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K-DURTM Microburst Release System[®]

(potassium chloride) Sustained Release Tablets

INDICATIONS AND USAGE: BECAUSE OF REPORTS OF INTESTINAL AND GASTRIC ULCERATION AND BLEEDING WITH SLOW-RELEASE POTASSIUM CHLORIDE PREPARATIONS, THESE DRUGS SHOULD BE RESERVED FOR THOSE PATIENTS WHO CANNOT TOLERATE OR REFUSE TO TAKE LIQUID OR EFFERVESCENT POTASSIUM PREPARATIONS OR FOR PATIENTS IN WHOM THERE IS A PROBLEM OF COMPLIANCE WITH THESE PREPARATIONS.

1. For therapeutic use in patients with hypokalemia with or without metabolic alkalosis, in digitalis intoxication and in patients with hypokalemic familial periodic paralysis.

2. For the prevention of potassium depletion when the dietary intake is inadequate in the following conditions: Patients receiving digitalis and diuretics for congestive heart failure, hepatic cirrhosis with ascites, states of aldosterone excess with normal renal function, potassium-losing nephropathy, and with certain diarrheal states.

3. The use of potassium salts in patients receiving diuretics for uncomplicated essential hypertension is often unnecessary when such patients have a normal dietary pattern. Serum potassium should be checked periodically, however, and if hypokalemia occurs, dietary supplementation with potassium-containing foods may be adequate to control milder cases. In more severe cases supplementation with potassium salts may be indicated.

CONTRAINDICATIONS: Potassium supplements are contraindicated in patients with hyperkalemia since a further increase in serum potassium concentration in such patients can produce cardiac arrest. Hyperkalemia may complicate any of the following conditions: Chronic renal failure, systemic acidosis such as diabetic acidosis, acute dehydration, extensive tissue breakdown as in severe burns, adrenal insufficiency, or the administration of a potassium-sparing diuretic (e.g., spironolactone, triamterene).

Wax-matrix potassium chloride preparations have produced esophageal ulceration in certain cardiac patients with esophageal compression due to enlarged left atrium.

All solid dosage forms of potassium chloride supplements are contraindicated in any patient in whom there is cause for arrest or delay in tablet passage through the gastrointestinal tract. In these instances, potassium supplementation should be with a liquid preparation.

WARNINGS: Hyperkalemia—In patients with impaired mechanisms for excreting potassium, the administration of potassium salts can produce hyperkalemia and cardiac arrest. This occurs most commonly in patients given potassium by the intravenous route but may also occur in patients given potassium orally. Potentially fatal hyperkalemia can develop rapidly and be asymptomatic. The use of potassium salts in patients with chronic renal disease, or any other condition which impairs potassium excretion, requires particularly careful monitoring of the serum potassium concentration and appropriate dosage adjustment.

Interaction with Potassium-Sparing Diuretics—Hypokalemia should not be treated by the concomitant administration of potassium salts and a potassium-sparing diuretic (e.g., spironolactone or triamterene) since the simultaneous administration of these agents can produce severe hyperkalemia.

Gastrointestinal Lesions—Potassium chloride tablets have produced stenotic and/or ulcerative lesions of the small bowel and deaths. These lesions are caused by a high localized concentration of potassium ion in the region of a rapidly dissolving tablet, which injures the bowel wall and thereby produces obstruction, hemorrhage or perforation.

K-DUR tablets contain micro-crystalloids which disperse upon disintegration of the tablet. These micro-crystalloids are formulated to provide a controlled release of potassium chloride. The dispersibility of the micro-crystalloids and the controlled release of ions from them are intended to minimize the possibility of a high local concentration near the gastrointestinal mucosa and the ability of the KCl to cause stenosis or ulceration. Other means of accomplishing this (e.g., incorporation of potassium chloride into a wax matrix) have reduced the frequency of such lesions to less than one per 100,000 patient years (compared to 40–50 per 100,000 patient years with enteric-coated potassium chloride) but have not eliminated them. The frequency of GI lesions with K-DUR tablets is, at present, unknown. K-DUR tablets should be discontinued immediately and the possibility of bowel obstruction or perforation considered if severe vomiting, abdominal pain, distention, or gastrointestinal bleeding occurs.

Metabolic Acidosis—Hypokalemia in patients with metabolic acidosis should be treated with an alkalinizing potassium salt such as potassium bicarbonate, potassium citrate, potassium acetate, or potassium gluconate.

PRECAUTIONS: The diagnosis of potassium depletion is ordinarily made by demonstrating hypokalemia in a patient with a clinical history suggesting some cause for potassium depletion. In interpreting the serum potassium level, the physician should bear in mind that acute alkalosis per se can produce hypokalemia in the absence of a deficit in total body potassium while acute acidosis per se can increase the serum potassium concentration into the normal range even in the presence of a reduced total body potassium. The treatment of potassium depletion, particularly in the presence of cardiac disease, renal disease, or acidosis requires careful attention to acid-base balance and appropriate monitoring of serum electrolytes, the electrocardiogram, and the clinical status of the patient.

Laboratory Tests: Regular serum potassium determinations are recommended. In addition, during the treatment of potassium depletion, careful attention should be paid to acid-base balance, other serum electrolyte levels, the electrocardiogram, and the clinical status of the patient, particularly in the presence of cardiac disease, renal disease, or acidosis.

Drug Interactions: Potassium-sparing diuretics; see **WARNINGS**.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term carcinogenicity studies in animals have not been performed.

Pregnancy Category C: Animal reproduction studies have not been conducted with K-DUR. It is also not known whether K-DUR can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. K-DUR should be given to a pregnant woman only if clearly needed.

Nursing Mothers: The normal potassium ion content of human milk is about 13 mEq per liter. Since oral potassium becomes part of the body potassium pool, so long as body potassium is not excessive, the contribution of potassium chloride supplementation should have little or no effect on the level in human milk.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: One of the most severe adverse effects is hyperkalemia (see **CONTRAINDICATIONS**, **WARNINGS**, and **OVERDOSSAGE**). There have also been reports of upper and lower gastrointestinal conditions including obstruction, bleeding, ulceration, and perforation (see **CONTRAINDICATIONS** and **WARNINGS**); other factors known to be associated with such conditions were present in many of these patients.

The most common adverse reactions to oral potassium salts are nausea, vomiting, abdominal discomfort, and diarrhea. These symptoms are due to irritation of the gastrointestinal tract and are best managed by taking the dose with meals or reducing the dose.

Skin rash has been reported rarely.

OVERDOSSAGE: The administration of oral potassium salts to persons with normal excretory mechanisms for potassium rarely causes serious hyperkalemia. However, if excretory mechanisms are impaired or if potassium is administered too rapidly intravenously, potentially fatal hyperkalemia can result (see **CONTRAINDICATIONS** and **WARNINGS**). It is important to recognize that hyperkalemia is usually asymptomatic and may be manifested only by an increased serum potassium concentration and characteristic electrocardiographic changes (peaking of T-waves, loss of P-waves, depression of S-T segment, and prolongation of the QT-interval). Late manifestations include muscle-paralysis and cardiovascular collapse from cardiac arrest.

Treatment measures for hyperkalemia include the following:

1. Elimination of foods and medications containing potassium and of potassium-sparing diuretics.
2. Intravenous administration of 300 to 500 ml/hr of 10% dextrose solution containing 10–20 units of insulin per 1,000 ml.

3. Correction of acidosis, if present, with intravenous sodium bicarbonate.

4. Use of exchange resins, hemodialysis, or peritoneal dialysis.

In treating hyperkalemia, it should be recalled that in patients who have been stabilized on digitalis, too rapid a lowering of the serum potassium concentration can produce digitalis toxicity.

our schools, for without it all our enterprises languish and our schemes for growing great and rich are blighted.

It is not only education that is required, but the right education, the sound mind in the sound body, neither to be dwarfed nor weakened, neither to be developed nor strengthened at the expense of the other; equally sacred, they equally claim our devoted care.

That physical and intellectual beauty of the highest type may be attained in the same individual, the Greek civilization, the highest the world has ever seen, marvellously proves.

How may we hope to attain like perfection? By guarding the school-house with the same religious care that we have over our hearthstones. We resent with all the vehemence of our nature any interference with our domestic life, and let us with the same righteous indignation forbid the presence of politicians in all school affairs. We know how insidious are the wiles of the men who so disinterestedly consent to conduct the public business for the dear people; how stealthily they extend their authority, encroaching now an inch, now an ell, now a rod upon the domain of private rights, unopposed, because what is everybody's business is nobody's business, characterizing the few protestants as grumblers and reactionists warring against the spirit of progress.

My friends, do not be deceived, politicians, however honest, ought not to be trusted with the management of public schools. Every community must have its own school board free from political taint, and responsible only to the people. I speak for this great commonwealth when I say to the politicians, stand back from this sacred ground. Do not undermine the very foundations upon which the fabric of society is reared; do not beat down that column which supports the feebleness of humanity.

Mr. President, and members of the State Medical Association of Alabama: I most cordially thank you for the honor you have conferred upon me, and in closing I say with fervent heart that I have a proud hope for the future of this Association. For the very humblest one of us there is a dazzling height that may be attained. Thirst for knowledge, self-respect, philanthropy, burning ambition, have made the great physicians and surgeons of the past. You can be just as great, for when this height has been reached, it will be seen that the successful aspirant has been stimulated by these strong powers. To him the laurel blossoms of renown, and the life giving mission of his art, are dearer and more attractive than was the mystic bough to the eager Æneas. On the eve of the battle of the Pyramids, Napoleon exclaimed: "Soldiers! from the height of yon monuments, forty centuries look down upon you." Gentlemen, the memory and life of countless worthies of our profession point and beckon to a goal more elevated than ever attracted legislators and conquerors, Solons and Cæsars.

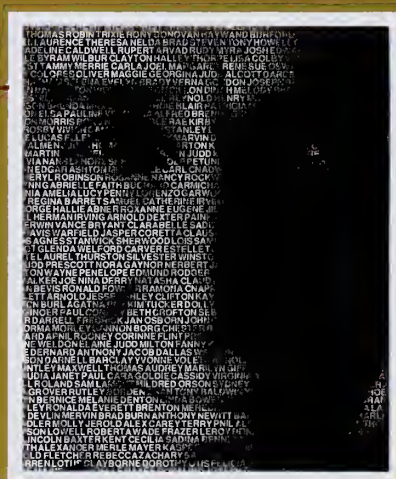
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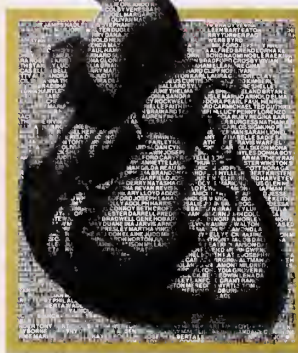
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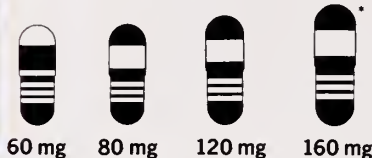
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BRIEF SUMMARY (FOR FULL PRESCRIBING INFORMATION, SEE PACKAGE CIRCULAR.)

INDERAL[®] LA brand of propranolol hydrochloride (Long Acting Capsules)

DESCRIPTION. Inderal LA is formulated to provide a sustained release of propranolol hydrochloride. Inderal LA is available as 60 mg, 80 mg, 120 mg, and 160 mg capsules.

CLINICAL PHARMACOLOGY. Inderal is a nonselective, beta-adrenergic receptor-blocking agent possessing no other autonomic nervous system activity. It specifically competes with beta-adrenergic receptor-stimulating agents for available receptor sites. When access to beta-receptor sites is blocked by Inderal, the chronotropic, inotropic, and vasodilator responses to beta-adrenergic stimulation are decreased proportionately.

Inderal LA Capsules (60, 80, 120, and 160 mg) release propranolol HCl at a controlled and predictable rate. Peak blood levels following dosing with Inderal LA occur at about 6 hours and the apparent plasma half-life is about 10 hours. When measured at steady state over a 24-hour period the areas under the propranolol plasma concentration-time curve (AUCs) for the capsules are approximately 60% to 65% of the AUCs for a comparable divided daily dose of Inderal Tablets. The lower AUCs for the capsules are due to greater hepatic metabolism of propranolol, resulting from the slower rate of absorption of propranolol. Over a twenty-four (24) hour period, blood levels are fairly constant for about twelve (12) hours then decline exponentially.

Inderal LA should not be considered a simple mg-for-mg substitute for conventional propranolol and the blood levels achieved do not match (are lower than) those of two to four times daily dosing with the same dose. When changing to Inderal LA from conventional propranolol, a possible need for retitration upwards should be considered especially to maintain effectiveness at the end of the dosing interval. In most clinical settings, however, such as hypertension or angina where there is little correlation between plasma levels and clinical effect, Inderal LA has been therapeutically equivalent to the same mg dose of conventional Inderal as assessed by 24-hour effects on blood pressure and on 24-hour exercise responses of heart rate, systolic pressure, and rate pressure product. Inderal LA can provide effective beta blockade for a 24-hour period.

INDICATIONS AND USAGE. **Hypertension:** Inderal LA is indicated in the management of hypertension; it may be used alone or used in combination with other antihypertensive agents, particularly a thiazide diuretic. Inderal LA is not indicated in the management of hypertensive emergencies.

Angina Pectoris Due to Coronary Atherosclerosis: Inderal LA is indicated for the long-term management of patients with angina pectoris.

Migraine: Inderal LA is indicated for the prophylaxis of common migraine headache. The efficacy of propranolol in the treatment of a migraine attack that has started has not been established and propranolol is not indicated for such use.

Hypertrophic Subaortic Stenosis: Inderal LA is useful in the management of hypertrophic subaortic stenosis, especially for treatment of exertional or other stress-induced angina, palpitations, and syncope. Inderal LA also improves exercise performance. The effectiveness of propranolol hydrochloride in this disease appears to be due to a reduction of the elevated outflow pressure gradient which is exacerbated by beta-receptor stimulation. Clinical improvement may be temporary.

CONTRAINDICATIONS. Inderal is contraindicated in 1) cardiogenic shock; 2) sinus bradycardia and greater than first-degree block; 3) bronchial asthma; 4) congestive heart failure (see WARNINGS) unless the failure is secondary to a tachyarrhythmia treatable with Inderal.

WARNINGS. **CARDIAC FAILURE:** Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive heart failure, and its inhibition by beta blockade may precipitate more severe failure. Although beta blockers should be avoided in overt congestive heart failure, if necessary, they can be used with close follow-up in patients with a history of failure who are well compensated and are receiving digitalis and diuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitalis on heart muscle.

IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta blockers can, in some cases, lead to cardiac failure. Therefore, at the first sign or symptom of heart failure, the patient should be digitalized and/or treated with diuretics, and the response observed closely, or Inderal should be discontinued (gradually, if possible).

IN PATIENTS WITH ANGINA PECTORIS, there have been reports of exacerbation of angina and, in some cases, myocardial infarction, following abrupt discontinuance of Inderal therapy. Therefore, when discontinuance of Inderal is planned, the dosage should be gradually reduced over at least a few weeks, and the patient should be cautioned against interruption or cessation of therapy without the physician's advice. If Inderal therapy is interrupted and exacerbation of angina occurs, it is usually advisable to reinstitute Inderal therapy and take other measures appropriate for the management of unstable angina pectoris. Since coronary artery disease may be unrecognized, it may be prudent to follow the above advice in patients considered at risk of having occult atherosclerotic heart disease who are given propranolol for other indications.

Nonallergic Bronchospasm (eg, chronic bronchitis, emphysema) — PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD IN GENERAL NOT RECEIVE BETA BLOCKERS. Inderal should be administered with caution since it may block bronchodilation produced by endogenous and exogenous catecholamine stimulation of beta receptors.

MAJOR SURGERY: The necessity or desirability of withdrawal of beta-blocking therapy prior to major surgery is controversial. It should be noted, however, that the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.

Inderal (propranolol HCl), like other beta blockers, is a competitive inhibitor of beta-receptor agonists and its effects can be reversed by administration of such agents, eg, dobutamine or isoproterenol. However, such patients may be subject to protracted severe hypotension. Difficulty in starting and maintaining the heartbeat has also been reported with beta blockers.

DIABETES AND HYPOGLYCEMIA: Beta blockers should be used with caution in diabetic patients if a beta-blocking agent is required. Beta blockers may mask tachycardia occurring with hypoglycemia, but other manifestations such as dizziness and sweating may not be significantly affected. Following insulin-induced hypoglycemia, propranolol may cause a delay in the recovery of blood glucose to normal levels.

THYROTOXICOSIS: Beta blockade may mask certain clinical signs of hyperthyroidism. Therefore, abrupt withdrawal of propranolol may be followed by an exacerbation of symptoms of hyperthyroidism, including thyroid storm. Propranolol may change thyroid function tests, increasing T₄ and reverse T₃, and decreasing T₃.

IN PATIENTS WITH WOLFF-PARKINSON-WHITE SYNDROME, several cases have been reported in which, after propranolol, the tachycardia was replaced by a severe bradycardia requiring a demand pacemaker. In one case this resulted after an initial dose of 5 mg propranolol.

PRECAUTIONS. **GENERAL:** Propranolol should be used with caution in patients with impaired hepatic or renal function. Inderal (propranolol HCl) is not indicated for the treatment of hypertensive emergencies.

Beta-adrenoreceptor blockade can cause reduction of intraocular pressure. Patients should be told that Inderal may interfere with the glaucoma screening test. Withdrawal may lead to a return of increased intraocular pressure.

CLINICAL LABORATORY TESTS: Elevated blood urea levels in patients with severe heart disease, elevated serum transaminase, alkaline phosphatase, lactate dehydrogenase.

DRUG INTERACTIONS: Patients receiving catecholamine-depleting drugs such as reserpine should be closely observed if Inderal (propranolol HCl) is administered. The added catecholamine-blocking action may produce an excessive reduction of resting sympathetic nervous activity which may result in hypotension, marked bradycardia, vertigo, syncope attacks, or orthostatic hypotension.

Caution should be exercised when patients receiving a beta blocker are administered a calcium-channel-blocking drug, especially intravenous verapamil, for both agents may depress myocardial contractility or atrioventricular conduction. On rare occasions, the concomitant intravenous use of a beta blocker and verapamil has resulted in serious adverse reactions, especially in patients with severe cardiomyopathy, congestive heart failure, or recent myocardial infarction.

Aluminum hydroxide gel greatly reduces intestinal absorption of propranolol.

Ethanol slows the rate of absorption of propranolol.

Phenyltoin, phenobarbital, and rifampin accelerate propranolol clearance.

Chlorpromazine, when used concomitantly with propranolol, results in increased plasma levels of both drugs.

Antipyrine and lidocaine have reduced clearance when used concomitantly with propranolol.

Thyroxine may result in a lower than expected T₃ concentration when used concomitantly with propranolol.

Cimetidine decreases the hepatic metabolism of propranolol, delaying elimination and increasing blood levels.

Theophylline clearance is reduced when used concomitantly with propranolol.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY: Long-term studies in animals have been conducted to evaluate toxic effects and carcinogenic potential. In 18-month studies in both rats and mice, employing doses up to 150 mg/kg/day, there was no evidence of significant drug-induced toxicity. There were no drug-related tumorigenic effects at any of the dosage levels. Reproductive studies in animals did not show any impairment of fertility that was attributable to the drug.

PREGNANCY: Pregnancy Category C. Inderal has been shown to be embryotoxic in animal studies at doses about 10 times greater than the maximum recommended human dose.

There are no adequate and well-controlled studies in pregnant women. Inderal should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

NURSING MOTHERS: Inderal is excreted in human milk. Caution should be exercised when Inderal is administered to a nursing woman.

PEDIATRIC USE: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS. Most adverse effects have been mild and transient and have rarely required the withdrawal of therapy.

Cardiovascular: Bradycardia; congestive heart failure; intensification of AV block; hypotension; paresthesia of hands; thrombocytopenic purpura; arterial insufficiency, usually of the Raynaud type.

Central Nervous System: Light-headedness; mental depression manifested by insomnia, lassitude, weakness, fatigue; reversible mental depression progressing to cataplexy; visual disturbances; hallucinations; vivid dreams; an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics. For immediate formulations, fatigue, lethargy, and vivid dreams appear dose related.

Gastrointestinal: Nausea, vomiting, epigastric distress, abdominal cramping, diarrhea, constipation, mesenteric arterial thrombosis, ischemic colitis.

Allergic: Pharyngitis and agranulocytosis, erythematous rash, fever combined with aching and sore throat, laryngospasm and respiratory distress.

Respiratory: Bronchospasm.

Hematologic: Agranulocytosis, nonthrombocytopenic purpura, thrombocytopenic purpura.

Auto-immune: In extremely rare instances, systemic lupus erythematosus has been reported.

Miscellaneous: Alopecia, L-like reactions, psoriasisiform rashes, dry eyes, male impotence, and Peyronie's disease have been reported rarely. Oculocutaneous reactions involving the skin, serous membranes and conjunctivae reported for a beta blocker (practolol) have not been associated with propranolol.

DOSEAGE AND ADMINISTRATION. Inderal LA provides propranolol hydrochloride in a sustained-release capsule for administration once daily. If patients are switched from Inderal Tablets to Inderal LA Capsules, care should be taken to assure that the desired therapeutic effect is maintained. Inderal LA should not be considered a simple mg-for-mg substitute for Inderal. Inderal LA has different kinetics and produces lower blood levels. Retitration may be necessary, especially to maintain effectiveness at the end of the 24-hour dosing interval.

HYPERTENSION — Dosage must be individualized. The usual initial dosage is 80 mg Inderal LA once daily, whether used alone or added to a diuretic. The dosage may be increased to 120 mg once daily or higher until adequate blood pressure control is achieved. The usual maintenance dosage is 120 to 160 mg once daily. In some instances a dosage of 640 mg may be required. The time needed for full hypertensive response to a given dosage is variable and may range from a few days to several weeks.

ANGINA PECTORIS — Dosage must be individualized. Starting with 80 mg Inderal LA once daily, dosage should be gradually increased at three- to seven-day intervals until optimal response is obtained. Although individual patients may respond at any dosage level, the average optimal dosage appears to be 160 mg once daily. In angina pectoris, the value and safety of dosage exceeding 320 mg per day have not been established.

If treatment is to be discontinued, reduce dosage gradually over a period of a few weeks (see WARNINGS).

MIGRAINE — Dosage must be individualized. The initial oral dose is 80 mg Inderal LA once daily. The usual effective dose range is 160-240 mg once daily. The dosage may be increased gradually to achieve optimal migraine prophylaxis. If a satisfactory response is not obtained within four to six weeks after reaching the maximal dose, Inderal LA therapy should be discontinued. It may be advisable to withdraw the drug gradually over a period of several weeks.

HYPERTROPHIC SUBAORTIC STENOSIS — 80-160 mg Inderal LA once daily.

PEDIATRIC DOSAGE — At this time the data on the use of the drug in this age group are too limited to permit adequate directions for use.

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An Epidemiologic Study of Maxillofacial Trauma at Carraway Methodist Medical Center, a Level I Trauma Center

Stephen E. Metzinger, M.D., M.S.P.D.;

Michael J. Naughton, M.D., Ph.D.;

Robert E. Howe, M.D.;

Paul S. Howard, M.D.

Abstract

This is an epidemiologic study of severe maxillofacial trauma looking at age, race, gender, mechanism of injury, mode of hospital transportation, seatbelt usage, alcohol use and seasonal variation in the incidence of facial injuries. We reviewed retrospectively severe maxillofacial trauma patients at Carraway Methodist Medical Center, a Level I Trauma Center, over a one-year period. This study encompasses patients from a three state area involving eighteen different counties and thirty-five cities. A total of fifty consecutive cases were included from August, 1986, through July, 1987.

Introduction

Trauma is the leading cause of death in the first four decades of life in the United States surpassed only by cancer and atherosclerosis as the cause of death in all age groups.^{1, 2, 4} The United States government estimates that more than one hundred fifty thousand deaths occur annually from accidents alone.⁵ However, unlike mortality for many serious diseases in the United

States the mortality from traumatic injuries is increasing each year.³ The cost for trauma care in the United States is staggering. Twelve percent of all hospital beds are occupied by trauma patients.^{2, 6} In 1981 the cost of death and disability due to trauma was eighty-seven billion dollars with forty-one billion attributed to death and disability secondary to motor vehicle accidents.^{1, 2, 3} Each year some two million people suffer

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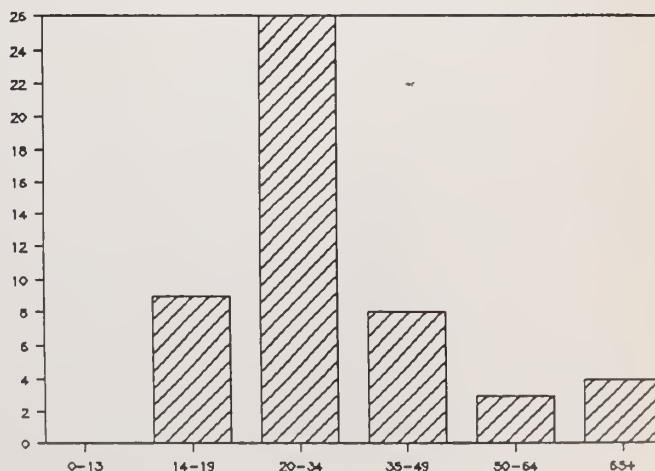


Figure 1.

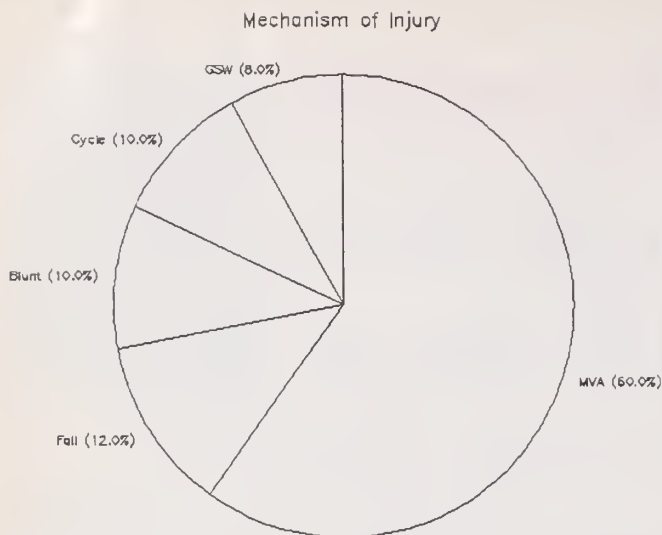


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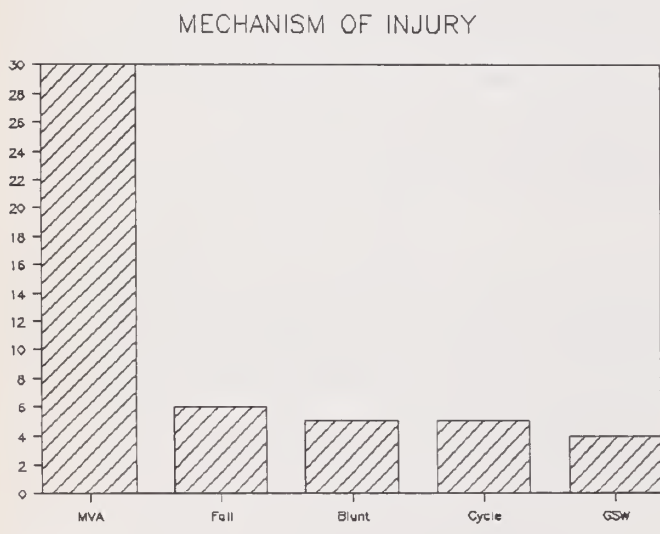


Figure 3.

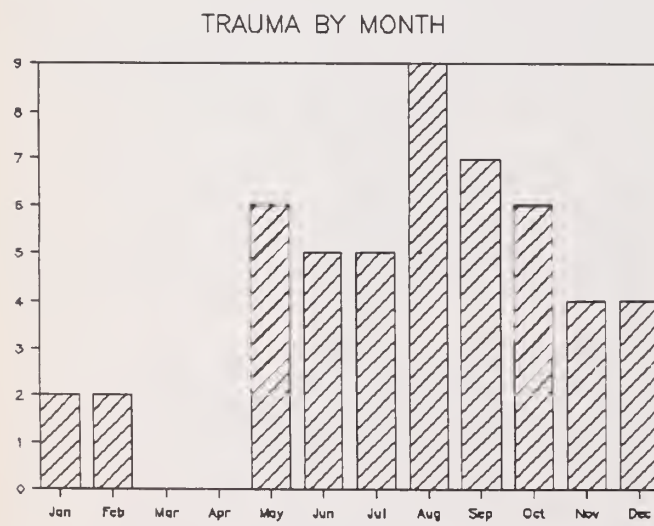


Figure 4.

death, injury or property damage because of a drunk driver.⁴ Moreover, about forty-one percent of all fatal crashes last year involved an intoxicated driver or pedestrian.⁴ It is clear from national data that vehicular trauma is both age and alcohol related. Our review of maxillofacial trauma in Alabama substantiates these observations and strongly relates facial trauma to the non-usage of seatbelts. Many states have recently passed mandatory seatbelt laws and our data clearly indicts the unused seatbelt as a major factor in severe facial injuries.

Patient Population

This is a retrospective review of maxillofacial trauma at the Carraway Methodist Medical Center, a Level I Trauma Center, over one year. Fifty consecutive patients with severe maxillofacial injuries requiring surgical intervention were reviewed. We examined age, race, gender, mechanism of injury, mode of hospital transportation, seatbelt usage and alcohol abuse as related to maxillofacial trauma. The techniques of facial reconstruction as well as the management of associated injuries will be the focus of a subsequent manuscript on facial injuries.

Results

1) Age: The mean age of this population was 32.5 years of age (Figure 1). The age breakdown was into six different categories. The zero to 13 age group had no patients. The 14 to 19 year-old age group had a total of 9 patients representing 18% of our population. The 20 to 34 year-old age group had a total of 26 patients representing 52% of our population. The 35 to 49 year-old age group had 8 patients representing 16% of our population. The 50 to 64 year-old age group had 3 patients representing 6% of our population and the 65 and over category had a total of 4 patients representing 8% of our study population. The majority of the patient population fell in the 20 to 34 year-old age bracket which correlates well with the national average.^{1, 2, 3, 4, 6} In our patient population 45 of the patients were Caucasian representing 90% of our patient population and 5 of the patients were black representing 10% of our patient population.

2) Gender Breakdown — male-female ratio: Seven patients in the population were black males which represented 70% of the total black population and 14% of the total population. Thirty patients in the study were white males which represented 75% of the white population and 60% of the total population. Both black males and white males combined represented 74% of total patient population. Black females numbered three which represented 30% of the black population and 6% of the total population. White females numbered ten representing 25% of the white population and 20% of the total population. Black female and white females combined represented 26% of the total population. The

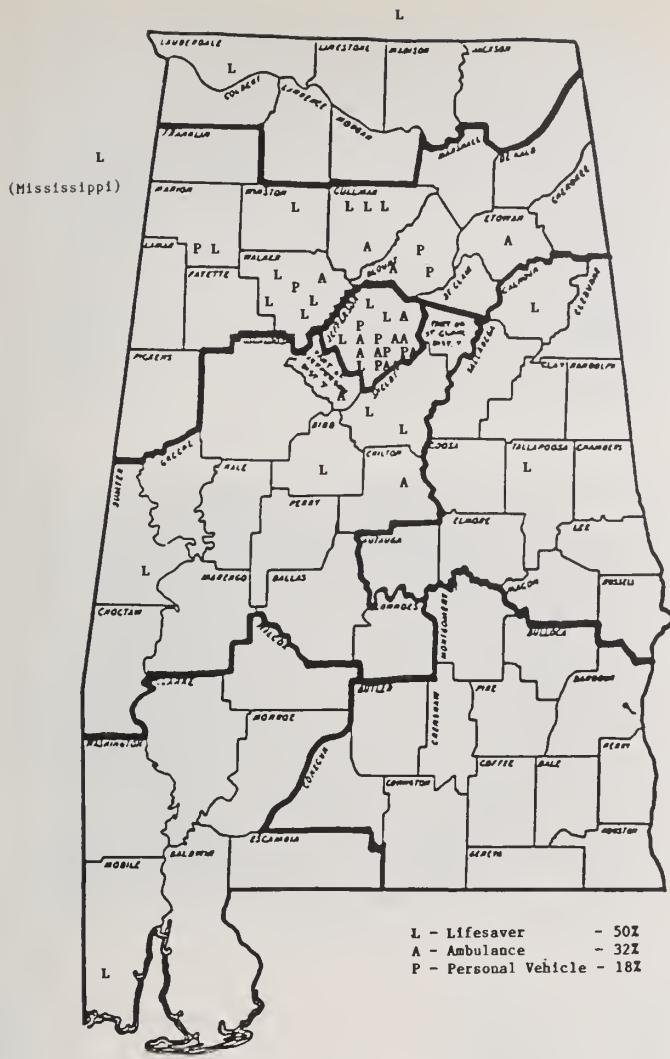


Figure 5.

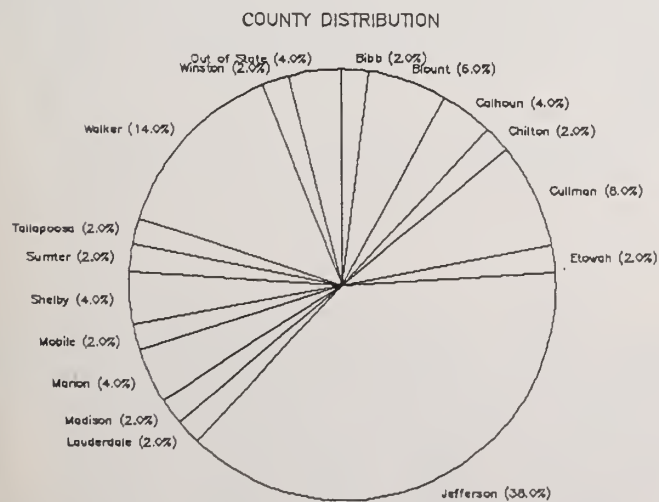


Figure 6.

data shows a 3 to 1 male predominance without statistical significance between blacks and whites based on gender.

3) Mechanism of Injury: Mechanism of injury was broken down into five different categories: motor vehicle accident (Figures 8, 9, 10), fall or fallen object (Figures 11, 12, 13, 14), motorcycle accident (Figures 15, 16), blunt assault (Figures 17, 18, 19) and gunshot wound (Figures 2, 3, 13, 14, 15, 16). The most frequently seen mechanism of injury was motor vehicular accident which represented 60% of our patient population. The second most frequent mechanism of injury was that of fall or falling objects which represented 12% of our patient population. Third most frequent was that of motorcycle accident which represent 10% of our population. Also, blunt assault represented 10% of our patient population and lastly gunshot wounds represented a total of 8% of our patient population. There is approximately a 3 to 1 male to female ratio in all five of the categories representing mechanism of injury.

4) Seasonal Incidence: It has long been suspected that major trauma occurred in seasonal patterns probably related to vehicular traffic.^{3, 8} Our impression has always been that the warm weather months were the busiest for trauma which is substantiated by our data (Figure 4). August and September accounted for 18% (9 patients) and 14% (7 patients) respectfully of our patients. Surprisingly we operated on no maxillofacial trauma during the months of March and April. This may represent either fewer cases of sufficient severity to require surgery or associated injuries (i.e., head trauma) so severe as to delay treatment or obviate surgical intervention altogether.

5) Mode of Transportation to Hospital: Since the recognition of the "golden hour" immediately after major trauma when specialized care can alter the outcome of the trauma victim, rapid evaluation and transport to a Level I Trauma Center has been achieved

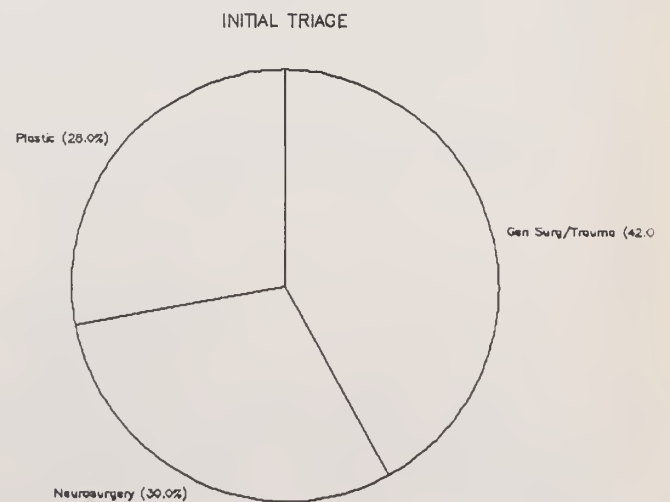


Figure 7.



Figure 8. Twenty-two year old, white female in motor vehicular accident not wearing seatbelt.



Figure 9. Miniplate fixation and primary cranial bone grafting of Le Fort III, Le Fort I and nasoethmoid facial fractures.



Figure 10. Six months postop further soft tissue reconstruction to face to follow.

with the use of aircraft, specifically the helicopter (Figure 5).^{3, 8} Fifty percent of our patients were transported via the Lifesaver helicopter air ambulance (Figure 24). Thirty-two percent of maxillofacial trauma cases were transported via ground ambulance and eighteen percent arrived by personal vehicle. Of all these cases which were received via the trauma room (Figure 25) forty-two percent of the patient population was initially admitted to the general surgery trauma service (Figure 7). An additional thirty percent was initially triaged to the neurosurgical service and twenty-eight percent were initially admitted to the plastic surgery service. Therefore, twenty-eight percent of the patient population initially seen in the trauma room had maxillofacial injuries so severe that this was the initial mode of triage. It is clear that multispecialty coverage is necessary for appropriate triage and expeditious surgical care on a 24-hour a day basis.

6) Geographic Distribution: This analysis encompasses patients from a three-state area. Ninety-six percent of the patient population came from the state of Alabama with two percent of the patient population coming from the state of Tennessee and two percent of the patient population coming from the state of

Mississippi. Sixteen different counties were represented in the state of Alabama (Figure 6). Within Alabama Jefferson County was our primary referral area with 19 patients representing 38% of the total population. Second was Walker County which had a total of seven patients representing fourteen percent of the patient population. Third was Cullman County with a total of four patients representing eight percent of the patient population and fourth was Blount County with a total of three patients representing six percent of the patient population. The map (Figure 5) summarizes our geographic referral base. Due to the presence of an air ambulance system for patient retrieval and a Level I trauma center, our referral area is expanded far beyond what would be predicted for a facility of 617 beds.

7) Seatbelts: Sixty percent of our maxillofacial trauma population was involved in a motor vehicular accident (Figure 2, 3). Of this number it is determined whether seatbelts were used in 73.3% or twenty-two of thirty cases. Of these twenty-two patients one hundred percent were not wearing their seatbelts at the time of their injuries (Figure 26). Although we are aware of no recent data concerning the multiple trauma patient

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Figure 11. Sixty-six year old, white female, a week status post blunt trauma to right side of face. Note typical presentation of patient with entrapment symptom causing diplopia.



Figure 15. Twenty-one year old, white male involved in motorcycle accident sustaining soft tissue injuries to nose, upper lip as well as a fractured mandible.



Figure 12. Limitation of upper gaze O.D.

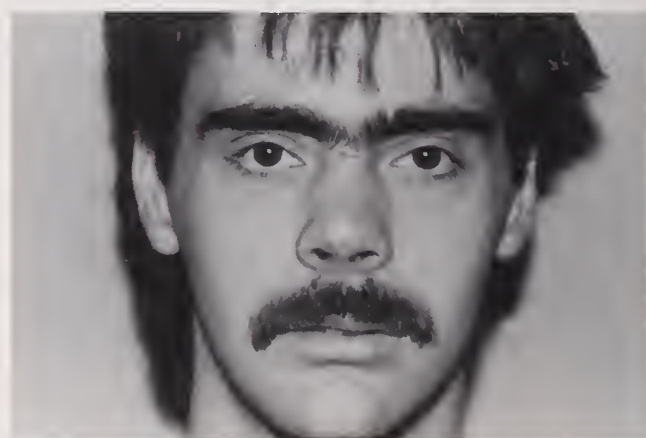


Figure 16. Six months postop.



Figure 13. Restoration of upper gaze s/p exploration and septal cartilage graft to orbital floor.



Figure 14. Four months postop.

and seatbelt usage, our information clearly and unequivocally correlates severe maxillofacial trauma and the lack of seatbelt usage.

8) Alcohol-related Trauma: Alcohol levels were determined in forty-eight percent or twenty-four of our patients. Seventy-one percent or seventeen of twenty-four patients tested positive for ETOH. The average alcohol level was 176.6 with a range from 23 to 299. In each individual area of breakdown it was attempted to determine ETOH level. In the area of blunt assault which represented ten percent of our patient population ETOH levels were not determined at the time of admission. In the gunshot wound population ethanol levels were determined in seventy-five percent of the patient population. Of those patients sixty-six percent tested positive for ethanol with an average level of 232.5 and a range of 175 to 290. In the motorcycle group forty percent of the patient population was tested for ethanol and all tests were positive.

In the motor vehicular accident population alcohol levels were determined in sixty percent of 18 patients and of that sixty percent two-thirds tested positive for



Figure 17. Fifty-three year old, black female sustaining blunt trauma to face as a result of assault.



Figure 18. Left zygomatic, orbital and maxillary fractures (displaced).



Figure 19. One-year postop miniplate fixation zygoma, primary cranial bone graft to orbital floor.

ETOH. The average alcohol level of this group was 190.82 and the range was from 33 to 299.

Conclusion

Governmental estimates tell us that more than 40% of all teenage deaths result from vehicular trauma and more than one-half of these accidents are alcohol related.^{4, 5, 6} Young people ages 15 to 24 make up only 19% of the population but constitute almost 37% of the alcohol related deaths in this country.^{3, 4} Two-thirds of our patients sustaining severe facial trauma due to vehicular accidents or blunt assault tested positive for alcohol usage. It is our impression that this may be a conservative estimate as all patients were not tested for serum alcohol levels. We also know that none of these drinking drivers and/or passengers were wearing seatbelts. It seems imminently clear to those of us who treat the trauma patient that without drinking and with proper seatbelt usage the incidence of severe facial trauma would be reduced.

We found a 3:1 male to female ratio regardless of the mechanism of injury to the face and no significant

racial predispositions. Geographically we see a vast majority of patients from Jefferson County and counties in northern Alabama. Fifty percent were air-evacuated by helicopter to our facility.

We clearly have shown that seatbelt usage and alcohol abuse are major factors associated with severe maxillofacial trauma. The age, sex and seasonal statistics confirm the national estimates as related to Alabama.^{3, 4} The air-ambulance has expanded our referral area and probably improved the care received by our patients especially during the "golden hour" period. Due to the significant volume of facial trauma treated by the Department of Plastic Surgery, we have developed and refined several new techniques of facial reconstruction^{7, 10, 14} including primary definitive osseous reconstruction^{8, 12} utilizing mini-plate techniques of fixation¹⁴ as well as primary cranial bone grafting⁹ of osseous defects. Our work indicates that early definitive repair of fractured orbitofacial structures improves aesthetic and functional results.^{10, 13} Our techniques for facial reconstruction in these fifty patient will be the subject of further manuscripts. □



Figure 20. Forty-eight year old, black male sustaining shotgun wound to the left side of face.



Figure 21. Damage to zygoma, orbit, zygomatic arch, lateral and inferior orbital walls.



Figure 24. Lifesaver air ambulance.



Figure 25. Trauma room during initial management and triage.

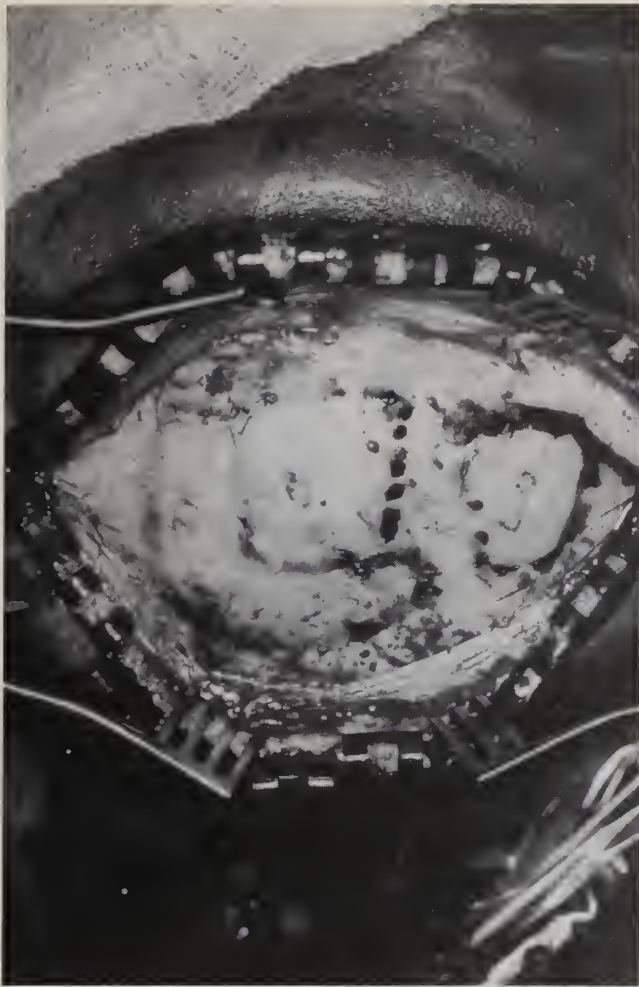


Figure 22. Intraoperative plan for reconstruction utilizing multiple contoured cranial bone grafts.



Figure 23. Osseous reconstruction at primary surgery.

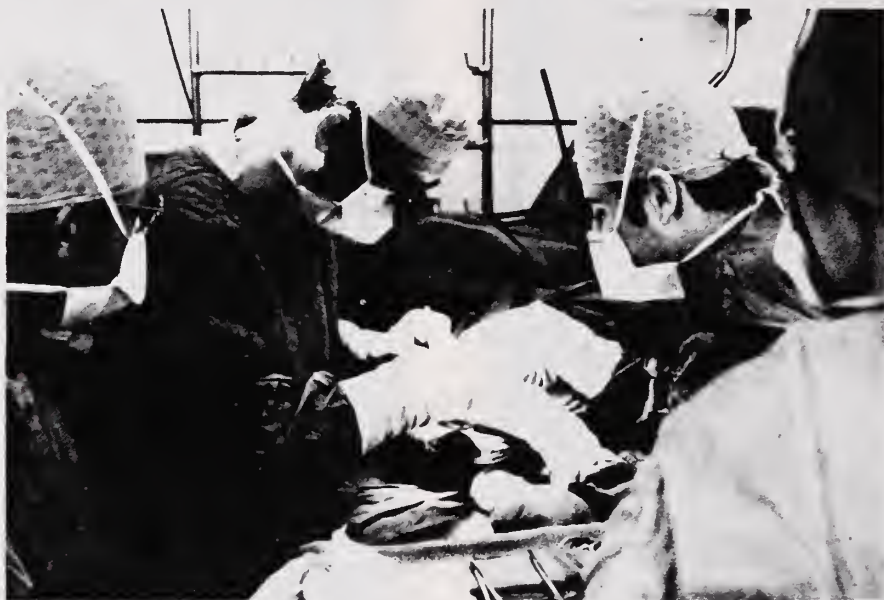


Figure 26. Dashboard as a result of victim not wearing seatbelt.

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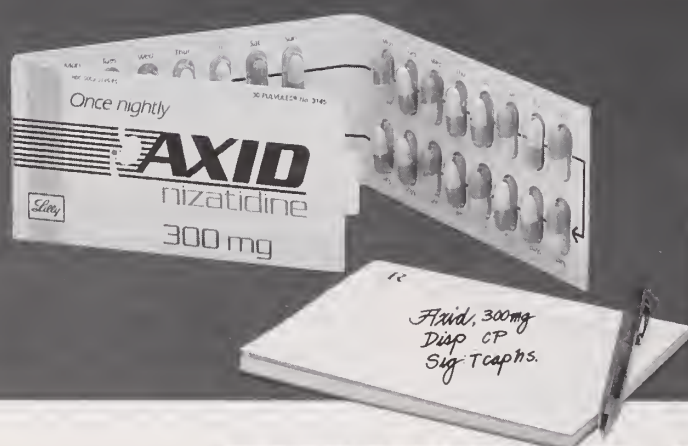
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2. Because nizatidine is excreted primarily by the kidney, dosage should be reduced in patients with moderate to severe renal insufficiency.

3. Pharmacokinetic studies in patients with hepatorenal syndrome have not been done. Part of the dose of nizatidine is metabolized in the liver. In patients with normal renal function and uncomplicated hepatic dysfunction, the disposition of nizatidine is similar to that in normal subjects.

Laboratory Tests—False-positive tests for urobilinogen with Multistix[®] may occur during therapy with nizatidine.

Drug Interactions—No interactions have been observed between Axid and theophylline, chlorazepoxide, lorazepam, lidocaine, phenytoin, and warfarin. Axid does not inhibit the cytochrome P-450-linked drug-metabolizing enzyme system, therefore, drug interactions mediated by inhibition of hepatic metabolism are not expected to occur. In patients given very high doses (3,900 mg) of aspirin daily, increases in serum salicylate levels were seen when nizatidine, 150 mg b.i.d., was administered concurrently.

Carcinogenesis, Mutagenesis, Impairment of Fertility—A two-year oral carcinogenicity study in rats with doses as high as 500 mg/kg/day (about 80 times the recommended daily therapeutic dose) showed no evidence of a carcinogenic effect. There was a dose-related increase in the density of enterochromaffin-like (ECL) cells in the gastric oxyntic mucosa. In a two-year study in mice, there was no evidence of a carcinogenic effect in male mice, although hyperplastic nodules of the liver were increased in the high dose males compared to placebo. Female mice given the high dose of Axid (2,000 mg/kg/day about 330 times the human dose) showed marginally statistically significant increases in hepatic carcinoma and hepatic nodular hyperplasia with no numerical increase seen in any of the other dose groups. The rate of hepatic carcinoma in the high dose animals was within the historical control limits seen for the strain of mice used. The female mice were given a dose larger than the maximum tolerated dose, as indicated by excessive (30%) weight decrement

compared to concurrent controls, and evidence of mild liver injury (transaminase elevations). The occurrence of a marginal finding at high dose only in animals given an excessive, and somewhat hepatotoxic dose, with no evidence of a carcinogenic effect in rats, male mice, and female mice (given up to 350 mg/kg/day, about 60 times the human dose), and a negative mutagenicity battery is not considered evidence of a carcinogenic potential for Axid.

Axid was not mutagenic in a battery of tests performed to evaluate its potential genetic toxicity, including bacterial mutation tests, unscheduled DNA synthesis, sister chromatid exchange, and the mouse lymphoma assay.

In a two-generation, perinatal and postnatal, fertility study in rats, doses of nizatidine up to 650 mg/kg/day produced no adverse effects on the reproductive performance of parental animals or their progeny.

Pregnancy—Teratogenic Effects—Pregnancy Category C—Oral reproduction studies in rats at doses up to 300 times the human dose, and in Dutch Belted rabbits at doses up to 55 times the human dose, revealed no evidence of impaired fertility or teratogenic effect, but, at a dose equivalent to 300 times the human dose, treated rabbits had abortions, decreased number of live fetuses, and depressed fetal weights. On intravenous administration to pregnant New Zealand White rabbits, nizatidine at 20 mg/kg produced cardiac enlargement, coarctation of the aortic arch, and cutaneous edema in one fetus and at 50 mg/kg it produced ventricular anomaly, distended abdomen, spina bifida, hydrocephaly, and enlarged heart in one fetus. There are, however, no adequate and well-controlled studies in pregnant women. It is also not known whether nizatidine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Nizatidine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers—Nizatidine is secreted and concentrated in the milk of lactating rats. Pups reared by treated lactating rats had depressed growth rates. Although no studies have been conducted in lactating women, nizatidine is assumed to be secreted in human milk, and caution should be exercised when nizatidine is administered to nursing mothers.

Pediatric Use—Safety and effectiveness in children have not been established. Use in Elderly Patients—Ulcer healing rates in elderly patients are similar to those in younger age groups. The incidence rates of adverse events and laboratory test abnormalities are also similar to those seen in other age groups. Age alone may not be an important factor in the disposition of nizatidine. Elderly patients may have reduced renal function.

Adverse Reactions: Clinical trials of nizatidine included almost 5,000 patients given nizatidine in studies of varying durations. Domestic placebo-controlled trials included over 1,900 patients given nizatidine and over 1,300 given placebo. Among the more common adverse events in the domestic placebo-controlled trials, sweating (1% vs 0.2%), urticaria (0.5% vs <0.01%), and somnolence (2.4% vs 1.3%) were significantly more common in the nizatidine group. A variety of less common events was also reported, it was not possible to

determine whether these were caused by nizatidine.

Hepatic—Hepatocellular injury, evidenced by elevated liver enzyme tests (SGOT [AST], SGPT [ALT], or alkaline phosphatase), occurred in some patients possibly or probably related to nizatidine. In some cases, there was marked elevation of SGPT. SGPT enzymes (greater than 500 IU/L), and in a single instance, SGPT was greater than 2,000 IU/L. The overall rate of occurrences of elevated liver enzymes and elevations to three times the upper limit of normal, however, did not significantly differ from the rate of liver enzyme abnormalities in placebo-treated patients. All abnormalities were reversible after discontinuation of Axid.

Cardiovascular—In clinical pharmacology studies, short episodes of asymptomatic ventricular tachycardia occurred in two individuals administered Axid and in three untreated subjects.

Endocrine—Clinical pharmacology studies and controlled clinical trials showed no evidence of antiandrogenic activity due to Axid. Impotence and decreased libido were reported with equal frequency by patients who received Axid and by those given placebo. Rare reports of gynecomastia occurred.

Hematologic—Fatal thrombocytopenia was reported in a patient who was treated with Axid and another H₂-receptor antagonist. On previous occasions, this patient had experienced thrombocytopenia while taking other drugs.

Integumental—Sweating and urticaria were reported significantly more frequently in nizatidine than in placebo patients. Rash and exfoliative dermatitis were also reported.

Other—Hyperuricemia unassociated with gout or nephrolithiasis was reported.

Overdosage: There is little clinical experience with overdosage of Axid in humans. If overdosage occurs, use of activated charcoal, emesis, or lavage should be considered along with clinical monitoring and supportive therapy. Renal dialysis for four to six hours increased plasma clearance by approximately 84%.

Test animals that received large doses of nizatidine have exhibited cholinergic-type effects, including lacrimation, salivation, emesis, miosis, and diarrhea. Single oral doses of 800 mg/kg in dogs and of 1,200 mg/kg in monkeys were not lethal. Intravenous LD₅₀ values in the rat and mouse were 301 mg/kg and 232 mg/kg respectively. (Nizatidine, Lilly) PV 2091 AMP [041288]

Axid[®] (nizatidine, Lilly)



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The Source of a Patient's Strength

In the news media today there are major concerns about how AIDS is spread, the cost of treatment, who should be tested and the fear of it. But we don't hear much about what the person with AIDS feels about his experience and his contact with the medical profession. One account of such a venture was shared with me by a person who has AIDS. He relates the ups and downs of his ordeal. When asked about this interview and how it would be published, he didn't hesitate. He said, "Anything I can do to help, I will be happy to." This is his story.

"The job I has was an easy job physically but I began to feel tired before the day was over. I developed a slight cold with a cough that wouldn't go away. I went to my doctor and when he did a chest x-ray, he found a patch of pneumonia. He insisted that I go into the hospital but the treatment didn't help much. He called in another physician who looked down into my lungs with a light. A few days later my doctor came into the room to break the news that I had a rare pneumonia called PCP and that my test for AIDS was positive.

"I went weak, I didn't know what to say. I had had no suspicions that I could have it. It was like all the strength had been pulled out of me. I did not want to see anyone and could not sleep. I needed help, and in those first few days there was no one I could talk to but my doctor.

"He told me the first thing I needed to do was to 'Get right with God.' I used to go to church but had not gone lately. I knew about God but had just never

called on Him much. He became my first strength and I couldn't have gotten through the ordeal without His help.

"Finally, I got enough strength to call my family together to tell them all at one time what I had. I felt that someone had already told them but with the exception of one or two they all accepted it and supported me. Since that time the rest of the family has come around.

"I was advised to make out a will and that was the hardest thing I have ever done. I prayed and cried and got on my knees and prayed some more. I begged for help. The Lord must have heard me and helped me through it. After I made my will, I felt better. At my age it had never occurred to me to think about a will or how I would divide my property. I wrote my will by hand in my hospital room and a relative carried it to the lawyer.

"That was about the time I completely bottomed out. I depended on my doctor a lot. I think I was his first patient with this and he was learning too. He would answer my questions but sometimes he would say, 'I'll have to get back with you on that.' He seemed to know more as the days went by and occasionally would say he had talked with the "Disease Center." I always felt I was in good hands. His attitude was always encouraging and he came to see me regularly. He arranged for the new medicine before he told me about it. I guess he wanted to make sure he could get it to keep me from further disappointment. He brought in a form for me to sign and said, 'I'll tell you now

before you sign it, the medicine is higher than hell.' I felt like I didn't have a choice. I finally accepted the fact that I had it and then I started getting better.

"The hospital nursing staff showed no resentment. They were very helpful, especially the infection control nurse. She had an upbeat approach that I needed. She talked with me and my family about the disease. She had a friendly attitude and used literature and a lot of explanation. She stressed little things like avoiding people who were sick with a cold. She taught me how AIDS is spread. I don't want anyone to catch it from me.

"The nurses were friendly with me after a few days. They were waiting to get to know me. They said they had heard of AIDS patients spitting in nurses faces but they realized I was not that type. Those patients must have been angry. Lord, I would not want to give anybody my disease.

"Most of my friends were very supportive but of course some have been hesitant. The most disappointment was with people who have been friends but would not even call on the telephone. Everybody knows you don't catch it on the phone.

"My doctor's office staff was completely at ease. The doctor must have talked with them. They would tease and showed no fear. I feel comfortable going there. They have been super! One of the last times I

was in I had gained ten pounds in six weeks and they kidded about getting fat. This gain in weight was caused by lying on the sofa and eating ice cream after my nausea left.

"My doctor has been great and I would encourage other doctors that treat patients like me to maintain a positive outlook and be supportive. It is desperately needed. And also provide the patient with plenty of information.

"I would urge other AIDS patients to talk with your doctors and counsellors, be informed and learn all you can about the disease. Keep a strong outlook and accept the fact that you have it but don't dwell on it.

"While in the hospital one of the nurses talked with me a lot about the disease and about how well I was handling it. As I was getting ready to go home she confessed that her brother has it but he would not go back to the doctor. He was frightened by something the doctor said and now refuses medical help. I told her I would be glad to talk to him if he wanted me to. She hugged my neck and wished me well. So far though, I haven't heard from him.

"I can't stay cooped up in the house all day. I go places and visit friends and family. Besides, the soaps on TV would drive me crazy."

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Before prescribing, see complete
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WARNING

This drug is not indicated for initial therapy of edema or hypertension. Edema or hypertension requires therapy titrated to the individual. If this combination represents the dosage so determined, its use may be more convenient in patient management. Treatment of hypertension and edema is not static, but must be reevaluated as conditions in each patient warrant.

Contraindications: Concomitant use with other potassium-sparing agents such as spironolactone or amiloride. Further use in anuria, progressive renal or hepatic dysfunction, hyperkalemia. Pre-existing elevated serum potassium. Hypersensitivity to either component or other sulfonamide-derived drugs.

Warnings: Do not use potassium supplements, dietary or otherwise, unless hypokalemia develops or dietary intake of potassium is markedly impaired. If supplementary potassium is needed, potassium tablets should not be used. Hyperkalemia can occur, and has been associated with cardiac irregularities. It is more likely in the severely ill, with urine volume less than one liter/day, the elderly and diabetics with suspected or confirmed renal insufficiency. Periodically, serum K⁺ levels should be determined. If hyperkalemia develops, substitute a thiazide alone, restrict K⁺ intake. Associated widened QRS complex or arrhythmia requires prompt additional therapy. Thiazides cross the placental barrier and appear in cord blood. Use in pregnancy requires weighing anticipated benefits against possible hazards, including fetal or neonatal jaundice, thrombocytopenia, other adverse reactions seen in adults. Thiazides appear and triamterene may appear in breast milk. If their use is essential, the patient should stop nursing. Adequate information on use in children is not available. Sensitivity reactions may occur in patients with or

without a history of allergy or bronchial asthma. Possible exacerbation or activation of systemic lupus erythematosus has been reported with thiazide diuretics.

Precautions: The bioavailability of the hydrochlorothiazide component of 'Dyazide' is about 50% of the bioavailability of the single entity. Theoretically, a patient transferred from the single entities of triamterene and hydrochlorothiazide may show an increase in blood pressure or fluid retention. Similarly, it is also possible that the lesser hydrochlorothiazide bioavailability could lead to increased serum potassium levels. However, extensive clinical experience with 'Dyazide' suggests that these conditions have not been commonly observed in clinical practice. Angiotensin-converting enzyme (ACE) inhibitors can elevate serum potassium; use with caution with 'Dyazide'. Do periodic serum electrolyte determinations (particularly important in patients vomiting excessively or receiving parenteral fluids, and during concurrent use with amphotericin B or corticosteroids or corticotropin[ACTH]). Periodic BUN and serum creatinine determinations should be made, especially in the elderly, diabetics or those with suspected or confirmed renal insufficiency. Cumulative effects of the drug may develop in patients with impaired renal function. Thiazides should be used with caution in patients with impaired hepatic function. They can precipitate coma in patients with severe liver disease. Observe regularly for possible blood dyscrasias, liver damage, other idiosyncratic reactions. Blood dyscrasias have been reported in patients receiving triamterene, and leukopenia, thrombocytopenia, agranulocytosis, and aplastic and hemolytic anemia have been reported with thiazides. Thiazides may cause manifestation of latent diabetes mellitus. The effects of oral anticoagulants may be decreased when used concurrently with hydrochlorothiazide; dosage adjustments may be necessary. Clinically insignificant reductions in arterial responsiveness to norepinephrine have been reported. Thiazides have also been shown to increase the paralyzing effect of nondepolarizing muscle relaxants such as tubocurarine. Triamterene is a weak folic acid antagonist. Do periodic blood studies in cirrhotics with splenomegaly. Antihypertensive effects may be enhanced in post-sympathectomy patients. Use cautiously in surgical patients. Triamterene has been found in renal stones in association with the other usual calculus components. Therefore, 'Dyazide' should be used with caution in patients with histories of stone formation. A few occurrences of acute renal failure have been reported in patients on 'Dyazide' when treated with indomethacin. Therefore, caution is advised in administering nonsteroidal anti-inflammatory agents with 'Dyazide'. The

following may occur: transient elevated BUN or creatinine or both, hyperglycemia and glycosuria (diabetic insulin requirements may be altered), hyperuricemia and gout, digitalis intoxication (in hypokalemia), decreasing alkali reserve with possible metabolic acidosis. 'Dyazide' interferes with fluorescent measurement of quinidine. Hypokalemia is uncommon with 'Dyazide', but should it develop, corrective measures should be taken such as potassium supplementation or increased dietary intake of potassium-rich foods. Corrective measures should be instituted cautiously and serum potassium levels determined. Discontinue corrective measures and 'Dyazide' should laboratory values reveal elevated serum potassium. Chloride deficit may occur as well as dilutional hyponatremia. Concurrent use with chlorpropamide may increase the risk of severe hyponatremia. Serum PBI levels may decrease without signs of thyroid disturbance. Calcium excretion is decreased by thiazides. 'Dyazide' should be withdrawn before conducting tests for parathyroid function. Thiazides may add to or potentiate the action of other antihypertensive drugs. Diuretics reduce renal clearance of lithium and increase the risk of lithium toxicity.

Adverse Reactions: Muscle cramps, weakness, dizziness, headache, dry mouth; anaphylaxis, rash, urticaria, photosensitivity, purpura, other dermatological conditions; nausea and vomiting, diarrhea, constipation, other gastrointestinal disturbances; postural hypotension (may be aggravated by alcohol, barbiturates, or narcotics). Necrotizing vasculitis, paresthesias, icterus, pancreatitis, xanthopsia and respiratory distress including pneumonitis and pulmonary edema, transient blurred vision, sialadenitis, and vertigo have occurred with thiazides alone. Triamterene has been found in renal stones in association with other usual calculus components. Rare incidents of acute interstitial nephritis have been reported. Impotence has been reported in a few patients on 'Dyazide', although a causal relationship has not been established.

Supplied: 'Dyazide' is supplied as a red and white capsule, in bottles of 1000 capsules; Single Unit Packages (unit-dose) of 100 (intended for institutional use only); in Patient-Pak[™] unit-of-use bottles of 100.

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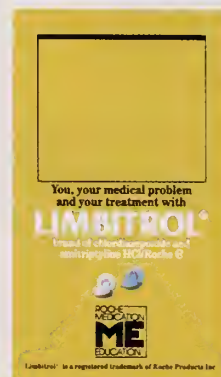
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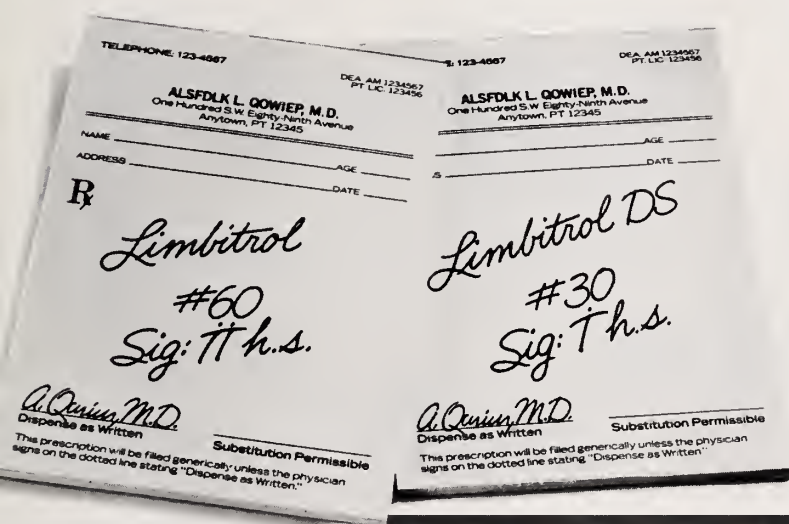
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References: 1. Data on file, Hoffmann-La Roche Inc., Nutley, NJ. 2. Feighner VP, et al: *Psychopharmacology* 61:217-225, Mar 22, 1979.

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Before prescribing, please consult complete product information, a summary of which follows:

Contraindications: Known hypersensitivity to benzodiazepines or tricyclic antidepressants; concomitant use with MAOIs or within 14 days of monoamine oxidase inhibitors (then initiate cautiously, gradually increasing dosage until optimal response is achieved); during acute recovery phase following myocardial infarction.

Warnings: Use with caution in patients with history of urinary retention or angle-closure glaucoma. Severe constipation may occur when used with anticholinergics. Closely supervise cardiovascular patients. Arrhythmias, sinus tachycardia, prolongation of conduction time, myocardial infarction and stroke reported with tricyclic antidepressants, especially in high doses. Caution patients about possible combined effects with alcohol and other CNS depressants and against hazardous occupations requiring complete mental alertness (e.g., operating machinery, driving).

Usage in Pregnancy: Use of minor tranquilizers during the first trimester should almost always be avoided because of increased risk of congenital malformations. Consider possibility of pregnancy when instituting therapy.

Withdrawal symptoms of the barbiturate type have occurred after discontinuation of benzodiazepines (see Drug Abuse and Dependence).

Precautions: Use cautiously in patients with a history of seizures, in hyperthyroid patients, those on thyroid medication, patients with impaired renal or hepatic function. Because of suicidal ideation in depressed patients, do not permit easy access to large quantities of drug. Periodic liver function tests and blood counts recommended during prolonged treatment. Amitriptyline may block action of guanethidine or similar antihypertensives. When tricyclic antidepressants are used concomitantly with cimetidine (Tagamet), clinically significant effects have been reported involving delayed elimination and increasing steady-state concentrations of the tricyclic drugs. Use of Limbitrol with other psychotropic drugs has not been evaluated; sedative effects may be additive. Discontinue several days before surgery. Limit concomitant administration of ECT to essential treatment. See Warnings for precautions about pregnancy. Should not be taken during the nursing period or by children under 12. In elderly and debilitated, limit to smallest effective dosage to preclude ataxia, oversedation, confusion or anticholinergic effects. Inform patients to consult physician before increasing dose or abruptly discontinuing this drug.

Adverse Reactions: Most frequent: drowsiness, dry mouth, constipation, blurred vision, dizziness, bloating. Less frequent: vivid dreams, impotence, tremor, confusion, nasal congestion. Rare: granulocytopenia, jaundice, hepatic dysfunction. Others: many symptoms associated with depression including anorexia, fatigue, weakness, restlessness, lethargy.

Adverse reactions not reported with Limbitrol but reported with one or both components or closely related drugs: **Cardiovascular:** Hypotension, hypertension, tachycardia, palpitations, myocardial infarction, arrhythmias, heart block, stroke. **Psychiatric:** Euphoria, apprehension, poor concentration, delusions, hallucinations, hypomania, increased or decreased libido. **Neurologic:** Incoordination, ataxia, numbness, tingling and paresthesias of the extremities, extrapyramidal symptoms, syncope, changes in EEG patterns. **Anticholinergic:** Disturbance of accommodation, paralytic ileus, urinary retention, dilatation of urinary tract. **Allergic:** Skin rash, urticaria, photosensitization, edema of face and tongue, pruritus. **Hematologic:** Bone marrow depression including agranulocytosis, eosinophilia, purpura, thrombocytopenia. **Gastrointestinal:** Nausea, epigastric distress, vomiting, anorexia, stomatitis, peculiar taste, diarrhea, black tongue. **Endocrine:** Testicular swelling, gynecomastia in the male, breast enlargement, galactorrhea and minor menstrual irregularities in the female, elevation and lowering of blood sugar levels, and syndrome of inappropriate ADH (antidiuretic hormone) secretion. **Other:** Headache, weight gain or loss, increased perspiration, urinary frequency, mydriasis, jaundice, alopecia, parotid swelling.

Drug Abuse and Dependence: Withdrawal symptoms similar to those noted with barbiturates and alcohol have occurred following abrupt discontinuance of chlordiazepoxide; more severe seen after excessive doses over extended periods; milder after taking continuously at therapeutic levels for several months. Withdrawal symptoms also reported with abrupt amitriptyline discontinuation. Therefore, after extended therapy, avoid abrupt discontinuation and taper dosage. Carefully supervise addiction-prone individuals because of predisposition to habituation and dependence.

Overdosage: Immediately hospitalize patient. Treat symptomatically and supportively. I.V. administration of 1 to 3 mg physostigmine salicylate may reverse symptoms of amitriptyline poisoning. See complete product information for manifestation and treatment.

How Supplied: Double strength (DS) Tablets, white, film-coated, each containing 10 mg chlordiazepoxide and 25 mg amitriptyline (as the hydrochloride salt), and Tablets, blue, film-coated, each containing 5 mg chlordiazepoxide and 12.5 mg amitriptyline (as the hydrochloride salt)—bottles of 100 and 500; Tel-E-Dose® packages of 100; Prescription Paks of 50.



ROCHE PRODUCTS INC.
Manatí, Puerto Rico 00701

In the depressed and anxious patient

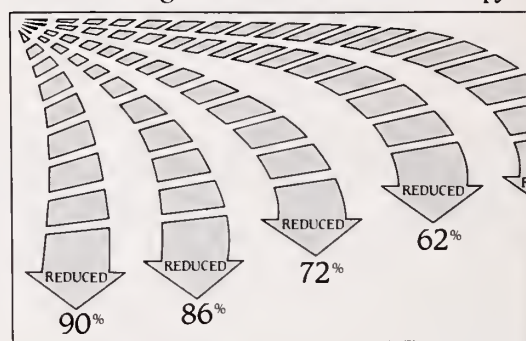
See Improvement In The First Week...¹

And The Weeks That Follow

- ➡ 74% of patients experienced improved sleep after the first *h.s.* dose¹
- ➡ First-week reduction in somatic symptoms¹

Caution patients about the combined effects of Limbitrol with alcohol or other CNS depressants and about activities requiring complete mental alertness, such as operating machinery or driving a car. In general, limit dosage to the lowest effective amount in elderly patients.

Percentage of Reduction in Individual Somatic Symptoms During First Week of Limbitrol Therapy*



*Patients often presented with more than one somatic symptom

Limbitrol[®]

Each tablet contains 5 mg chlordiazepoxide and 12.5 mg amitriptyline (as the hydrochloride salt) (IV)

Limbitrol DS[®]

Each tablet contains 10 mg chlordiazepoxide and 25 mg amitriptyline (as the hydrochloride salt) (IV)

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